# AMENDED EXHIBIT E

Part 1

## **Summary of Key Karen Frank Testimony**

Karen Frank was the PSC's expert on pharmacovigilance. That is the specialty of evaluating complaints made by hospitals, doctors, and patients about a drug (adverse event reports) to assess whether they signal a problem with the product. Her role was to comment on the adequacy of Actavis' pharmacovigilance process and any signal detection for Digitek®. (K. Frank dep. @ 70).

As a starting place, the FDA has never found that there was a signal of problems with Digitek®. Despite Form 483s and warning letters on other regulatory issues, there are none on this topic. In 2009, on its website, the FDA specifically discussed the Digitek® recall and said:

Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that **ALL** potentially affected amounts of Digitek® tablets have been recalled. In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.

See "Facts and Myths About Generic Drugs," July 9, 2009, FDA website, available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm, attached hereto.

If Actavis produced substantial quantities of defective Digitek®, there would have been an unusual number of cases of digoxin toxicity somewhere in the United States. The Plaintiffs' general causation expert, Dr. Semigran, was unaware of any reported literature from any source saying there was. See M. Semigran dep. @ 23; see also D. Bliesner dep. @ 207-208; J. Farley dep. @ 368-369; M. Kenny dep. @180; D. Nelson @ 29, 54.

So, did Karen Frank find some hidden signal in the adverse event reporting data that Actavis supposedly ignored? No.

First, she did not even come up with her own opinions. The PSC told her what they wanted, and she tried to support it. (K. Frank dep. @ 247-250). Second, despite being asked about signal detection, the PSC did not give her any information that would allow her to perform such an analysis. (K. Frank dep. @ 70, 72-74). Third, in her view, while the PSC spent "lots" of time in deposition with Actavis company witnesses on general regulatory compliance issues, there was little specific to Digitek®. She was, therefore, "unable to subset out information on the systems specifically for Digitek®." (K. Frank dep. @ 17-20). Fourth, because of the first three issues, Dr. Frank became very concerned about whether her "opinions" were even supported by sufficient data. (K. Frank dep. @ 83-85). Finally, as a result, she did not even fully stand by her report. (K. Frank dep. @ 219-221).

# FDA U.S. Food and Drug Administration

Home> Drugs> Resources for You> Information for Consumers (Drugs)

### Drugs

Facts and Myths about Generic Drugs

Today, 7 in 10 prescriptions filled in the United States are for generic drugs. This fact sheet explains how generic drugs are made and approved and debunks some common myths about these products.

FACT: FDA requires generic drugs to have the same quality and performance as the brand name drugs.

- · When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency. Some variability can and does occur during manufacturing, for both brand name and generic drugs. When a drug, generic or brand name, is mass produced, very small variations in purity, size, strength and other parameters are permitted. FDA puts limits on how much variability in composition or performance of a drug is acceptable.
- · Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name (or reference) product. Generic drugs do not need to contain the same inactive ingredients as the brand product.
- Through review of bioequivalence data, FDA assures that the generic product will perform the same as its respective brand name (or reference product. This standard applies to all generic drugs, whether immediate or controlled release.
- A generic drug must be shown to be bioequivalent to the reference drug; that is, it must be shown to give blood levels that are very similar to those of the reference product. If blood levels are the same, the therapeutic effect will be the same. In that case, there is no need to carry ou a clinical effectiveness study and they are not required.
- · All generic manufacturing, packaging and testing sites must pass the same quality standards as those of brand name drugs and the generic products must meet the same exacting specifications as any innovator brand name product. In fact, many generic drugs are made in the same plants as innovator brand name drug products.
- If an innovator of a brand name drug switches drug production to an alternative manufacturing site, or they change formulation of their brand name drug, these companies are held to the same rigorous manufacturing requirements as those that apply to generic drug companies.

### FACT: Research shows that generics work just as well as brand name drugs.

 A recent study evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand-name counterparts. There was no evidence that brand-name heart drugs worked any better than generic heart drugs. [Kesseiheim et al. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21)

FACT: When it comes to price, there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 80 to 85% lower than the brand name product.

- An IMS National Prescription Audit shows that a typical formulary now charges \$6 for generic medications, \$29 for preferred branded drugs, and \$40 or more for non-preferred branded drugs. [Aitken et al. Prescription drug spending trends in the United States: looking beyond the turning point. Health Aff (Millwood). 2009;28(1):w151-60].
- . Independent research has shown that total prescription drug expenditures in the United States only increased by 4.0% from 2006 to 2007, wit total spending rising from \$276 billion to \$287 billion. This is a sharp decrease from the 8.9% growth rate observed in prescription drug expenditures in 2006. One factor cited as a reason for the slowdown is an increase in availability and use of generic drugs [Hoffman et al. Projecting future drug expenditures--2009. Am J Health Syst Pharm. 2009;66(3):237-57].

Recently, some misinformation has raised concerns over generic drugs. Below are some common myths in circulation.

MYTH: FDA lets generic drugs differ from the brand name counterpart by up to 45 percent.

FACT: This claim is false. Anyone who repeats this myth does not understand how FDA reviews and approves generic drugs.

- FDA recently evaluated 2,070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs into a person's body. These studies were submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name was only 3.5 percent [Davit et al. Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43(10):1583-97]. Some generics were absorbed slightly more, some slightly less. This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name. In fact, there have been studies in which branded drugs were compared with themselves as well as with a generic. As a rule, the difference for the generic-to-brand comparison was about the same as the brand-to-brand comparison.
- · Any generic drug modeled after a single, brand name drug (the reference) must perform approximately the same in the body as the brand name drug. There will always be a slight, but not medically important, level of natural variability – just as there is for one batch of brand name drug to the next.

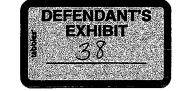
MYTH: People who are switched to a generic drug are risking treatment failure.

FACT: There is no evidence for this claim. Treatment failures can and do occur when taking generic or brand name drugs. If someone is switched to a generic drug around the time they are relapsing, they may attribute the problem to the switch.

- Many people who have recovered from major depression have a relapse despite continued treatment. These relapses have been shown in trials of long-term therapy. (Byrne and Rothschild. Loss of antidepressant efficacy during maintenance therapy: possible mechanisms and treatments. J Clin Psychiatry. 1998;59(6):279-88].
- Many people who are on a seizure medications will re-experience a seizure despite continued treatment. [Randomised study of antiepileptic drug withdrawal in patients in remission. Medical Research Council Antiepileptic Drug Withdrawal Study Group. Lancet. 1991;337(8751):1175-
- A percentage of people will re-experience gastric ulcers, despite an initial, positive response to and continued treatment with prescription strength antacids (cimetidine tablets; http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=8131#nlm34067-<sup>1</sup>9).

MYTH: Generic drugs cost less because they are inferior to brand name drugs.

FACT: Generic manufacturers are able to sell their products for lower prices, not because the products are of lesser quality, but because generic manufacturers generally do not engage in costly advertising, marketing and promotion, or significant research and development.



 When a brand name drug comes off patent and generic drugs are permitted to compete with the brand name drug, the generic products compete by offering lower prices. Unlike the manufacturers of brand name drugs, generic drug companies do not have significant expenses to recoup for advertising, marketing and promotion, or research and development activities.

MYTH: There are quality problems with generic drug manufacturing. A recent recall of generic digoxin (called Digitek) shows that generic drugs put patients at risk.

FACT: FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs - generic and brand name are held.

- In March 2008, FDA performed a scheduled inspection of the Actavis production facility and identified products that were not manufactured to required specifications over a period of time extending back to the year 2006. Included in this list of products was one particular lot of Digitek.
- Actavis detected a very small number of oversized tablets in this lot (specifically, 20 double-sized tablets in a sample of approximately 4.8 million tablets).
- Although Actavis attempted to remove the affected Digitek tablets through visual inspection, FDA determined that this method of removal was inadequate to assure the product's quality and consistency in accordance with the current Good Manufacturing Practice (cGMP) regulations.
- Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that ALL potentially affected lots of Digitek tablets have been recalled. In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.
- FDA takes action whenever we find that a drug manufacturer is not following cGMPs. Over the last ten years, FDA has taken enforcement action against many brand name and generic firms for failing to meet FDA manufacturing quality standards.

MYTH: FDA's enforcement action against the generic drug company Ranbaxy demonstrates quality problems with imported generic

FACT: FDA's action demonstrates FDA's commitment to safe generic drugs.

- FDA has taken several regulatory actions against the generic drug manufacturer Ranbaxy, on the basis of problems at two of Ranbaxy's manufacturing facilities. Ranbaxy is one of many non-U.S. based generic and brand drug manufacturers.
- . On Sept. 2008, the FDA issued two warning letters and instituted an Import Alert barring the entry of all finished drug products and active pharmaceutical ingredients from Ranbaxy's Dewas, Paonta Sahib and Batamandi Unit facilities due to violations of U.S. cGMP requirements. That action barred the commercial importation of 30 different generic drugs into the United States and remains in effect today (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149532.htm²).
- Subsequent FDA investigations also revealed a pattern of questionable data raising significant questions regarding the reliability of certain generic drug applications from Ranbaxy.
- To address the allegedly falsified data, the FDA has invoked its Application Integrity Policy (AIP) against the Paonta Sahib facility. When the AII is implemented, the FDA stops all substantive scientific review of any new or pending drug approval applications that contain data generated by the Paonta Sahib facility. This AIP covers applications that rely on data generated by the Paonta Sahib facility only.
- In the fiscal year 2008, FDA performed 2,221 drug-related inspections. FDA takes many different enforcement actions, not just against generic drug manufacturers. For a list of enforcement actions in the fiscal year 2008, see http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129812.pdf3. It is FDA's responsibility to ensure that the

drugs people use, generic or brand name, are safe and effective.

MYTH: Brand name drugs are safer than generic drugs.

FACT: FDA receives very few reports of adverse events about specific generic drugs. Most reports of adverse events are related to side effects of the drug ingredient itself.

. The monitoring of postmarket adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. In most cases, reports of adverse events generally describe a known reaction to the active drug

MYTH: FDA does not care about concerns over generic drugs.

FACT: FDA is actively engaged in making all regulated products - including generic drugs - safer.

- We are aware that there are reports noting that some people may experience an undesired effect when switching from brand name drug to a generic formulation or from one generic drug to another generic drug. Evidence indicates that if problems with interchangeability of drug formulations occur, they occur only for a very small subset of people.
- FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. The Agency does not have the resources to perform independent clinical studies, and lacks the regulatory authority to require industry to conduct such studies. FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises.

### Links on this page:

- 1. http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=8131#nlm34067-
- 2. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149532.htm
- 3. http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129812.pdf

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IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MDL CASE NO. 2:09-cv-121 MDL 1968

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

BOBBY R. MILLIGAN, ET AL.,

PLAINTIFFS :

:

v.

:

ACTAVIS GROUP HF, ET AL.,

DEFENDANTS :

DEPOSITION OF MARC J. SEMIGRAN, M.D., a witness called on behalf of the Defendant, Actavis Group, HF, pursuant to the provisions of the Federal Rules of Civil Procedure, before Lisa McDonald Valdario, (CSR #130093), a Registered Professional Reporter and Notary Public in and for the Commonwealth of Massachusetts, held at the Holiday Inn Boston at Beacon Hill, 5 Blossom Street, Boston, Massachusetts 02114, on Wednesday, June 23, 2010, commencing at 10:04 a.m.

Page 23 with some number of people, right? 1 2 Α Correct. Did you ever do any study of the Mass. General 3 statistics to see if there was any spike in 4 diagnoses of digoxin toxicity in 2005, 6, 7 or 8? 5 Did not. 6 Α Are there people at Mass. General who watch for 7 0 trends like that? 8 There is a quality assurance program. 9 Α sure. I do not know if that's one of their 10 charges. 11 Well, given your administrative positions and your 12 clinical positions, if there had been some spike 13 in the diagnoses of digoxin toxicity in those 14 years, do you think that's something that would 15 have come to your attention? 16 I can only say possibly. It's a large 17 Α organization, and often times there are things I 18 think should have come to my attention earlier 19 than they do, that I eventually find out about, 20 21 so. There are probably things that I might think 22 should come to my attention that do not. 23 Your CV, because of its length, was a bit much to 24 get through all the publications. Have you ever 25

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

MDL NO: 1968

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION,

100 N. Tampa Street Suite 2900 Tampa, FL 33602 February 18, 2011 at 8:15 a.m.

VIDEOTAPE DEPOSITION OF DAVID BLIESNER, Ph.D.

Taken on behalf of the Defendants before

PHILIP RYAN, RPR, Court Reporter, Notary Public in

and for the State of Florida at Large, pursuant to

Defendant's Notice of Taking Deposition in the

above cause.

		Page 207
1	a specific problem? I'm sorry a specific	01:52
2	product.	01:52
3	A. Well, I don't work for the FDA and I'm	01:52
4	not going to speak for the FDA, but if they	01:52
5	find go back look at the EIRs and see that	01:52
6	there are all kinds of problems with respect to	01:52
7	manufacturing records and lack of manufacturing	01:52
8	records, validated processes and things like	01:52
9	that. So that's what they do.	01:52
10	They put if the question as to the	01:52
11	integrity of the manufactured product, then, you	01:52
12	know, they take action.	01:52
13	Q. What question were you just answering?	01:52
14	I move to strike that as completely	01:52
15	non-responsive.	01:52
16	Were you talking about Activis or their	01:52
17	records somehow?	01:52
18	A. I'm talking about the records that the	01:52
19	FDA reviewed and their systems and places that	01:52
20	will show up on the establishment inspection	01:52
21	report.	01:52
22	Q. Are you an expert in GMP compliance or	01:52
23	not?	01:53
24	A. Am I am, sir.	01:53
25	Q. Okay. I'm asking you a question about	01:53

17 A. les.  18 Q. If the FDA wanted to determine whether 01:53  19 that GMP deficiency impacted a particular product, 01:53  20 how would they do that? 01:53  21 A. They may or may not start looking at all 01:54  22 of the quality systems that are in there. I'm 01:54  23 just telling you how they do it. They could stop 01:54  24 when they see significant deficiencies and there 01:54			
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17 A. Tes.  18 Q. If the FDA wanted to determine whether 01:53  19 that GMP deficiency impacted a particular product, 01:53  20 how would they do that? 01:53  21 A. They may or may not start looking at all 01:54  22 of the quality systems that are in there. I'm 01:54  23 just telling you how they do it. They could stop 01:54  24 when they see significant deficiencies and there 01:54	16	assess; right?	01:53
that GMP deficiency impacted a particular product,  19 that GMP deficiency impacted a particular product,  20 how would they do that?  21 A. They may or may not start looking at all  22 of the quality systems that are in there. I'm  23 just telling you how they do it. They could stop  24 when they see significant deficiencies and there  25 on the quality systems deficiencies and there  26 on the quality systems that are in there. I'm  27 on the quality systems deficiencies and there  28 on the quality systems deficiencies and there  29 on the quality systems deficiencies and there  20 on the quality systems deficiencies and there	17	A. Yes.	01:53
how would they do that?  A. They may or may not start looking at all  of the quality systems that are in there. I'm  of the quality systems that are in there of the quality systems that are in the could stop  when they see significant deficiencies and there  on:54	18	Q. If the FDA wanted to determine whether	01:53
20 now would they do that:  21 A. They may or may not start looking at all  22 of the quality systems that are in there. I'm  23 just telling you how they do it. They could stop  24 when they see significant deficiencies and there  25 of the quality systems that are in there. I'm  26 of the quality systems that are in there. I'm  27 of the quality systems that are in there ould stop  28 of the quality systems that are in there. I'm  29 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  21 of the quality systems that are in there. I'm  22 of the quality systems that are in there. I'm  23 of the quality systems that are in there. I'm  24 of the quality systems that are in there. I'm  25 of the quality systems that are in there. I'm  26 of the quality systems that are in there. I'm  27 of the quality systems that are in there. I'm  28 of the quality systems that are in there. I'm  29 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  29 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  29 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in there. I'm  20 of the quality systems that are in the quality systems that are	19	that GMP deficiency impacted a particular product,	01:53
21 A. They may of may not start from 22 of the quality systems that are in there. I'm 01:54 23 just telling you how they do it. They could stop 01:54 24 when they see significant deficiencies and there 01:54	20	how would they do that?	01:53
just telling you how they do it. They could stop  24 when they see significant deficiencies and there  01:54	21	A. They may or may not start looking at all	01:54
23 just telling you now they do it. They sould be 24 when they see significant deficiencies and there 01:54	22	of the quality systems that are in there. I'm	01:54
24 when they see significant deficiencies what's 01:54	23	just telling you how they do it. They could stop	01:54
25 is doubt in their mind they just stop. That's 01:54	24	when they see significant deficiencies and there	01:54
	25	is doubt in their mind they just stop. That's	01:54

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IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY
LITIGATION

MDL NO. 1968

### VOLUME II

The continued videotaped deposition of JAMES J.

FARLEY taken by counsel for the Defendants, Actavis

Totowa, LLC, Actavis, Inc., and Actavis Elizabeth, LLC,

pursuant to notice and by agreement of counsel, reported

by Angela S. Garrett, CSR, RPR, B-2407, at the Embassy

Suites, 145 Mulberry Boulevard, Savannah, Georgia, on

January 19, 2011, commencing at 9:03 a.m.

```
Page 368
                   How about 483s?
               0
1
                   Yes.
2
               А
                   Warning letters?
 3
               0
               Α
                   Yes.
 4
                   Recalls?
               0
 5
                   Yes.
 6
               Α
                   Have you seen any -- have you -- I'm
 7
               0
             Let me rephrase that.
 8
     sorry.
               Have you been provided with any scientific
 9
     information whatsoever that there was a spike in Digoxin
10
     toxicity at hospitals, nursing homes, poison control
11
     centers or outpatient facilities in -- at any point
12
     between 2005 and 2008?
13
                   I'm not sure what you mean by Digoxin
14
     toxicity.
15
                   Do you have any idea what that means?
16
               0
                    You mean OD, overdosing, or too much
17
     strength? I mean, Digoxin when used properly is not
18
     toxic. And to say Digoxin toxicity, if you mean
19
     over-strength tablets -- I'm not -- let me not put
20
21
     words -- please tell me again.
                    Digoxin toxicity simply for the purpose of
22
               Q
     my question is somebody who has a toxic reaction to
23
     Digoxin, whether the -- regardless of what the dose is.
24
     Okay?
25
```

```
Page 369
               What I'm asking you is whether you've been
 1
     provided with any scientific proof that there was a
 2
     spike in Digoxin toxicity at any sort of medical
 3
     facility in the United States between 2005 and 2008.
 4
               Α
                   No.
 5
                    MR. ERNST: I'm going to object, vague,
 6
           ambiguous, calls for speculation.
 7
                    MR. KERENSKY: When you get to a breaking
 8
           point I'd like to take a break.
 9
                    MR. ERNST: Scientific proof is not a
10
           standard.
11
                    MR. MORIARTY: Now is fine.
12
                    THE VIDEOGRAPHER: Okay. We're going off
13
14
           the --
                    MR. MORIARTY: Mike wants to take a
15
           break, Don. So we're going to do that.
16
                    THE VIDEOGRAPHER: Going off record.
17
           This is the end of Tape No. 1. 9:55.
18
                 (A brief recess was taken.)
19
                    THE VIDEOGRAPHER: Okay. We're back on
20
           record.
                    It's 10:11 and this is the beginning of
21
           Media Unit No. 2.
22
23
     BY MR. MORIARTY:
                   Mr. Farley, this is Exhibit 57 from your
24
               0
     first deposition. This is a Form 483, is it not?
25
```

Page 1

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MDL No. 1968

IN RE:

DIGITEK PRODUCT

LIABILITY LITIGATION

VIDEOTAPED

DEPOSITION OF:

MARK G. KENNY

VOLUME I

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before CAROL ANN SHEPARD, a Certified Court Reporter of the State of New Jersey, held at the MARRIOTT NEWARK AIRPORT HOTEL, 1 Hotel Road, Newark, New Jersey, on Tuesday, June 29, 2010, commencing at 8:30 in the forenoon.

```
Page 180
    do with the information.
1
                  Have you read the depositions of any
2
           0.
3
     doctors --
                  No.
4
           Α.
                  -- who have been taken in this case?
5
           Q.
                       I have no interest.
                  No.
           Α.
6
                  Do you know from any independent
7
           0.
     research whether any hospital reported an increased
8
     incidence of Digoxin toxicity in the years 2005,
9
     '06, '07 or '08?
10
                  I did no investigation of any sort, so
11
           Α.
     the answer is I know of nothing, because I didn't do
12
13
     anything.
                  Does that make sense?
14
                  All right. Let me get back to some
15
           Ο.
     statistics that I was asking you about before.
16
                   Of this 688.2 million tablets that were
17
     part of the recall, do you have any opinion, to a
18
     reasonable probability, as to what percentage of
19
     them were outside the USP specifications on the low
20
21
     side?
                   On the low side?
22
           Α.
                   I have no way of knowing that.
23
                   Do you have any opinion, to a
24
           0.
     probability, of what percentage of those tablets
25
```

Rennillo Deposition & Discovery 216.523.1313 www.rennillo.com 888.391.3376 (Depo)

Page 1

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

\* \* \*

IN RE: DIGITEK PRODUCT LIABILITY

LITIGATION

MDL NO. 1968

\* \* \*

Deposition of EJORN D. NELSON, PHARM.D., Witness herein, called by the Defendants for cross-examination pursuant to the Rules of Civil Procedure, taken before me, Mary Jo Stevens, a Notary Public in and for the State of Ohio, at the Doubletree Cincinnati Airport, 2826 Terminal Drive, Hebron, Kentucky, on Tuesday, the 22nd day of June, 2010, at 8:22 a.m.

\* \* \*

Page 29 thing as official consulting privileges. 1 I know is that since 1972 physicians from that 2 hospital and other hospitals routinely ask for 3 and receive a consultation and advice from me 4 and other specialists in toxicology at the 5 poison center. 6 Do you officially take call at any 7 Q. hospitals? 8 No. 9 Α. Have you ever studied any of the 10 0. University of Cincinnati Medical Center 11 statistics to see if there was a spike in 12 complaints about digoxin any time between 2005 13 and the first half of 2008? 14 No. 15 Α. In looking at Exhibit 41, your CV, 0. 16 I did not see that any of the articles that you 17 published were directly about digoxin. Were 18 there any? 19 Α. Yes. 20 Tell me which ones are directly 21 Ο. about digoxin. 22 Okay. Page nine, number three. 23 Α. Let's stop there for a second. 24 0. Does that just have a section about digoxin --25

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Page 54

- 1 reactions. If you give a drug and something
- 2 peculiar happens at the same time, you have a
- 3 high index of suspicion that giving the
- 4 medication might have had something to do with
- 5 it. It is a complex judgment-heavy area of
- 6 undertaking and it requires some experience and
- 7 knowledge of the patient's pathophysiologic
- 8 condition and the effects of the medication --
- 9 of medications that the patient is taking.
- 10 Q. And you certainly want to rule out
- 11 other potential factors of the adverse event,
- 12 correct?
- 13 A. If possible, yes.
- 14 Q. I asked you before whether you had
- 15 studied the University of Cincinnati's
- 16 statistics and whether they had had a spike of
- 17 digoxin. Did you do any study like that at the
- 18 poison center?
- 19 A. No.
- Q. Do you know how many calls the
- 21 poison center received after the April 25th
- 22 recall regarding Digitek?
- 23 A. I do not.
- Q. Do you know how many calls the
- 25 poison center received prior to April 25th,

Videotaped

June 30, 2010

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT

LIABILITY LITIGATION

MDL NO. 1968

Videotaped deposition of KAREN A. FRANK, M.D., taken at the law offices of SEGAL McCAMBRIDGE SINGER & MAHONEY, LTD., 1818 Market Street, Suite 2600, Philadelphia, Pennsylvania, on Wednesday, June 30, 2010, commencing at 9:10 a.m., before Dianna R. Pugliese, a Registered Merit Reporter, Certified Realtime Reporter, Certified Shorthand Reporter (NJ & DE), and Notary Public, pursuant to notice.

Rennillo Deposition & Discovery www.rennillo.com 888.391.3376 (Depo)

June 30, 2010

	Page 2		Page
1 APPEARANCES		1	COURT REPORTER: Are there any
FOR THE PLAINTIFF:  Mr. Fred Thompson, III		2	stipulations for the record?
Motley Rice LLC	1	3	MR. DEAN: No.
4 28 Bridgeside Boulevard Mount Pleasant, South Carolina 29464	1	4	VIDEO OPERATOR: We're now on the video
5 843-216-9118 6	1	5	record.
7 FOR THE DEFENDANTS:	1	6	This is the videotape deposition of
8 Mr. Richard A. Dean Tucker Ellis & West LLP	l	7	Karen A. Frank, M.D., taken by the Defendant, In Re:
9 1150 Huntington Building	1	8	Digitek Product Liability Litigation, in the United
925 Euclid Avenue 10 Cleveland, Ohio 44115-1475	l	9	States District Court for the Southern District of
216-696-2137 11		10	West Virginia, Charleston Division, held at the
12 Ms. Monee A. Takla		11	offices of Segal McCambridge Singer & Mahoney, Ltd
Tucker Ellis & West LLP 13 515 South Flower Street, 42nd Floor		12	1818 Market Street, Philadelphia, Pennsylvania, on
Los Angeles, California 90071		13	Wednesday, June 30, 2010.
14 213-430-3378 15		14	The time is 9:10 a.m.
Mr. Harvey L. Kaplan		15	I am David Williams, the videographer.
255 Grand Boulevard			The court reporter is Dianna Pugliese. We are from
17 Kansas City, Missouri 64108 816-474-6550		16	the firm of Rennillo Court Reporting in Cleveland,
18		17	
19 ALSO PRESENT: David Williams, Video Operator		18	Ohio.
20		19	Counsel, will you now please introduce
EXAMINATION INDEX 21		20	yourselves.
KAREN A. FRANK, M.D. 22 BY MR. DEAN 5		21	MR. DEAN: My name is Richard Dean. I
BY MR. KAPLAN 247		22	represent the Actavis defendants.
23 BY MR. THOMPSON 268 BY MR. KAPLAN 286		23	MS. TAKLA: Monee Takla for the Actavis
24 BY MR. DEAN 297		24	defendants.
BY MR. KAPLAN 302 25		25	MR. KAPLAN: Harvey Kaplan, Shook, Hard
1	Page 3		Page
1 EXHIBIT INDEX		1	& Bacon, for Mylan.
2 MARKED D		2	MR. THOMPSON: Fred Thompson, Motle
3 250 Digitals Expert Table of Contents with 45		3	Rice, for Plaintiffs.
250 Digitek Expert Table of Contents with 45 4 18 items listed		4	VIDEO OPERATOR: The reporter will not
5 251 Table of Contents with 11 items 45 listed	-	5	swear in the witness.
6		6	KAREN A. FRANK, M.D., having been du
252 Handwritten notes by Dr. Frank, four 47 pages		7	
	I	,	sworn, was examined and testified as follows:
8 253 Handwritten notes by Dr. Frank, 24 47	***************************************	8	sworn, was examined and testified as follows:  EXAMINATION
			EXAMINATION
8 253 Handwritten notes by Dr. Frank, 24 47 pages 9 254 Handwritten notes by Dr. Frank, one 47		8	
8 253 Handwritten notes by Dr. Frank, 24 47 pages 9 254 Handwritten notes by Dr. Frank, one 47 10 page		8 9	EXAMINATION BY MR. DEAN: Q. Good morning.
8 253 Handwritten notes by Dr. Frank, 24 47 pages 9 254 Handwritten notes by Dr. Frank, one 47 10 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages		8 9 10	EXAMINATION BY MR. DEAN: Q. Good morning. A. Good morning.
8 253 Handwritten notes by Dr. Frank, 24 47 pages 9 254 Handwritten notes by Dr. Frank, one 47 10 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages		8 9 10 11	EXAMINATION BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the
8 253 Handwritten notes by Dr. Frank, 24 47 pages  254 Handwritten notes by Dr. Frank, one 47 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages 12 256 Handwritten notes of Karen Frank, one 55 page		8 9 10 11 12	EXAMINATION BY MR. DEAN: Q. Good morning. A. Good morning.
8 253 Handwritten notes by Dr. Frank, 24 47 pages  9 254 Handwritten notes by Dr. Frank, one 47 10 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages 12 256 Handwritten notes of Karen Frank, one 55 page 14 257 Engagement Agreement with Smart 58 Consulting Group, LLC, six pages		8 9 10 11 12 13	EXAMINATION BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank.
8 253 Handwritten notes by Dr. Frank, 24 47 pages  9 254 Handwritten notes by Dr. Frank, one 47 10 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages  12 256 Handwritten notes of Karen Frank, one 55 13 page 14 257 Engagement Agreement with Smart 58 Consulting Group, LLC, six pages		8 9 10 11 12 13 14	EXAMINATION BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank. Q. And it's Dr. Frank; correct?
8 253 Handwritten notes by Dr. Frank, 24 47 pages  254 Handwritten notes by Dr. Frank, one 47  10 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages  12 256 Handwritten notes of Karen Frank, one 55 page 14 257 Engagement Agreement with Smart 58 Consulting Group, LLC, six pages  15 258 Digitek Case Overview, 11 pages 59		8 9 10 11 12 13 14 15	EXAMINATION BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank. Q. And it's Dr. Frank; correct? A. Yes.
8 253 Handwritten notes by Dr. Frank, 24 47 pages  9 254 Handwritten notes by Dr. Frank, one 47 10 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages  12 256 Handwritten notes of Karen Frank, one 55 page 14 257 Engagement Agreement with Smart 58 Consulting Group, LLC, six pages  15 258 Digitek Case Overview, 11 pages 59 16 259 Handwritten notes by Dr. Frank, one 60		8 9 10 11 12 13 14 15 16	EXAMINATION  BY MR. DEAN:  Q. Good morning.  A. Good morning.  Q. Would you state your full name for the record, please?  A. Karen Ann Frank.  Q. And it's Dr. Frank; correct?  A. Yes.  Q. Dr. Frank, we met before, but my name is
8 253 Handwritten notes by Dr. Frank, 24 47 pages  254 Handwritten notes by Dr. Frank, one 47 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages 12 256 Handwritten notes of Karen Frank, one 55 page 14 257 Engagement Agreement with Smart Consulting Group, LLC, six pages 15 258 Digitek Case Overview, 11 pages 59 16 259 Handwritten notes by Dr. Frank, one 60 17 page 18 260 Handwritten notes by Dr. Frank, one 60		8 9 10 11 12 13 14 15 16 17	EXAMINATION  BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank. Q. And it's Dr. Frank; correct? A. Yes. Q. Dr. Frank, we met before, but my name is Richard Dean.
8 253 Handwritten notes by Dr. Frank, 24 47 pages  254 Handwritten notes by Dr. Frank, one 47 page 255 Index titled Documents Sent to Karen 53 Frank, two pages  12 256 Handwritten notes of Karen Frank, one 55 page 14 257 Engagement Agreement with Smart Consulting Group, LLC, six pages  15 258 Digitek Case Overview, 11 pages 59  16 259 Handwritten notes by Dr. Frank, one 60 page 18 260 Handwritten notes by Dr. Frank, one 60 page		8 9 10 11 12 13 14 15 16 17 18	EXAMINATION  BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank. Q. And it's Dr. Frank; correct? A. Yes. Q. Dr. Frank, we met before, but my name is Richard Dean. Have you ever had your deposition taken
8 253 Handwritten notes by Dr. Frank, 24 47 pages  254 Handwritten notes by Dr. Frank, one 47 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages 12 256 Handwritten notes of Karen Frank, one 55 page 14 257 Engagement Agreement with Smart Consulting Group, LLC, six pages 15 258 Digitek Case Overview, 11 pages 59 16 259 Handwritten notes by Dr. Frank, one 60 page 18 260 Handwritten notes by Dr. Frank, one 60 page 19 261 Color photocopy of Dr. Frank's report 69		8 9 10 11 12 13 14 15 16 17 18 19	EXAMINATION  BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank. Q. And it's Dr. Frank; correct? A. Yes. Q. Dr. Frank, we met before, but my name is Richard Dean. Have you ever had your deposition taken before?
8 253 Handwritten notes by Dr. Frank, 24 47 pages  254 Handwritten notes by Dr. Frank, one 47 page 255 Index titled Documents Sent to Karen 53 Frank, two pages  256 Handwritten notes of Karen Frank, one 55 page 257 Engagement Agreement with Smart 58 Consulting Group, LLC, six pages  258 Digitek Case Overview, 11 pages 59  259 Handwritten notes by Dr. Frank, one 60 page 260 Handwritten notes by Dr. Frank, one 60 page		8 9 10 11 12 13 14 15 16 17 18 19 20 21	EXAMINATION  BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank. Q. And it's Dr. Frank; correct? A. Yes. Q. Dr. Frank, we met before, but my name is Richard Dean. Have you ever had your deposition taken before? A. No.
8 253 Handwritten notes by Dr. Frank, 24 47 pages  254 Handwritten notes by Dr. Frank, one 47 page 255 Index titled Documents Sent to Karen 53 Frank, two pages  256 Handwritten notes of Karen Frank, one 55 page 257 Engagement Agreement with Smart Consulting Group, LLC, six pages  258 Digitek Case Overview, 11 pages 59  259 Handwritten notes by Dr. Frank, one 60 page 260 Handwritten notes by Dr. Frank, one 60 page 261 Color photocopy of Dr. Frank's report titled Digitek Recall, Assessment of Pharmacovigilance Systems and Risk Communication, Background, Analysis		8 9 10 11 12 13 14 15 16 17 18 19 20 21	EXAMINATION  BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank. Q. And it's Dr. Frank; correct? A. Yes. Q. Dr. Frank, we met before, but my name is Richard Dean. Have you ever had your deposition taken before? A. No. Q. So this is your very first deposition
8 253 Handwritten notes by Dr. Frank, 24 47 pages  9 254 Handwritten notes by Dr. Frank, one 47 10 page 11 255 Index titled Documents Sent to Karen 53 Frank, two pages  12 256 Handwritten notes of Karen Frank, one 55 page 14 257 Engagement Agreement with Smart 58 Consulting Group, LLC, six pages  15 258 Digitek Case Overview, 11 pages 59 16 259 Handwritten notes by Dr. Frank, one 60 page 18 260 Handwritten notes by Dr. Frank, one 60 page 19 261 Color photocopy of Dr. Frank's report titled Digitek Recall, Assessment of Pharmacovigilance Systems and Risk		8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	EXAMINATION  BY MR. DEAN:  Q. Good morning.  A. Good morning.  Q. Would you state your full name for the record, please?  A. Karen Ann Frank.  Q. And it's Dr. Frank; correct?  A. Yes.  Q. Dr. Frank, we met before, but my name is Richard Dean.  Have you ever had your deposition taken before?  A. No.  Q. So this is your very first deposition ever; correct?
8 253 Handwritten notes by Dr. Frank, 24 47 pages  254 Handwritten notes by Dr. Frank, one 47 page  10 255 Index titled Documents Sent to Karen 53 Frank, two pages  12 256 Handwritten notes of Karen Frank, one 55 page 14 257 Engagement Agreement with Smart Consulting Group, LLC, six pages  15 258 Digitek Case Overview, 11 pages 59  16 259 Handwritten notes by Dr. Frank, one 60 page  18 260 Handwritten notes by Dr. Frank, one 60 page  261 Color photocopy of Dr. Frank's report titled Digitek Recall, Assessment of Pharmacovigilance Systems and Risk Communication, Background, Analysis and Conclusions, 6/15/2010		8 9 10 11 12 13 14 15 16 17 18 19 20 21	EXAMINATION  BY MR. DEAN: Q. Good morning. A. Good morning. Q. Would you state your full name for the record, please? A. Karen Ann Frank. Q. And it's Dr. Frank; correct? A. Yes. Q. Dr. Frank, we met before, but my name is Richard Dean. Have you ever had your deposition taken before? A. No. Q. So this is your very first deposition

2 (Pages 2 to 5)

	Page 6		Page 8
1	front of a jury before?	1	not to write the report, but to get ready for the
2	A. No.	2	deposition.
3	Q. Has Mr. Thompson or someone else on	3	What is it that you did to get ready for
4	behalf of the plaintiffs had a chance to tell you	4	the deposition today?
5	about the deposition process a little bit?	5	A. I reread these two documents yesterday.
6	A. Yes.	6	Q. And by these two documents, for the
7	Q. Okay. Well, let me just go over a few	7	record, you are referring to what I've marked already
8	ground rules.	8	as Defendant's Exhibits 49 and 50; is that correct?
9	I'm going to be asking you some	9	A. Yes. I went back and reviewed to
10	questions today, so it's very important that the two	10	refresh my memory.
11	of us communicate. So if I ask you a question that	11	Q. Well, actually, 40 just so we're
12	you do not understand, will you tell me that?	12	clear, 49 is a copy of your resume; correct?
13		13	A. No.
	<ul><li>A. Yes.</li><li>Q. Your responses have to be verbal, out</li></ul>	14	Q. No?
14		15	A. This what I reviewed was a copy of
15	loud. We can't this court reporter, at least,	16	the Conclusion.
16	can't take the shaking or nodding of the head in a	17	Q. Right.
17	particular direction.	18	A. And I went through this document. I
18	So will you speak up and use whatever	I	can't say that I went through it a hundred percent. I
19	words you want to use, but please speak up and give	19 20	went through key sections where I wanted to refresh my
20	your answer verbally?	l	
21	A. Yes.	21	memory.
22	Q. And I understand you're not you're a	22	Q. And for the record, what you have is the
23	little bit under the weather today?	23	long document we've marked as Exhibit 50 to this
24	A. Yes.	24	deposition; is that correct?
25	Q. At any point if you need a break for any	25	A. Yes.
	Page 7	-	Page 9
1	reason, just let us know and we'll take a break.	1	Q. And I compared them before. Your
2	Okay.	2	document has 70 pages and Exhibit 50 also has 70
3	A. Uh-huh.	3	pages, so they are the same.
4	Q. Yes?	4	A. There should be no alterations between
5	A. Yes.	5	what you received and what I printed.
6	Q. What have you done to prepare for the	6	Q. So what you did in preparation for the
7	deposition today?	7	deposition was to review what we marked as Exhibit 50;
8	A. I was sent a set of volumes of printed	8	correct?
9	material. I went through them generally, and then I	9	A. I don't know why this is not marked as
10	went through them looking for white space or blanks	10	an exhibit, because this is the key opinion. This was
11	with information that I thought should be there that	11	at one point one document. And at the request of Pete
12	was not there.	12	Miller, it was split. So he asked me to address two
13	I met with Pete Miller and Megan Carter	13	separate issues
14	over lunch, and I presented them with a list of	14	Q. Let me just interrupt. I won't do that
15	documents that I would liked to have seen, and they	15	often, but I want to make sure we get this exhibit
16	referenced it against what was available in discovery	16	marked correctly.
17	and they sent me two more printed volumes, electronic	17	The shorter document that you have in
18	copies of everything I had electronic copies of.	18	front of you is are you telling me that's not
19	And then one final Establishment	19	included in Exhibit 50?
20	Inspection Report.	20	A. Yes. It is not included in Exhibit 50.
21	MR. KAPLAN: One final what?	21	Q. Okay. Can I see it, please?
22	THE WITNESS: Establishment Inspection	22	A. Yes. (Document provided.)
23	Report.	23	Q. Dr. Frank, I have just reviewed the
24	BY MR. DEAN:	24	first 11 pages of Exhibit 50 and it it would
25	Q. My question was, what you did to get	25	those first set of pages would appear to be exactly

	Page 10		Page 12
1	what is in the shorter document.	1	there is the one combined document and then the two
2	A. Okay.	2	separate documents that were sent to Pete Miller by
3	Q. Is there a difference?	3	e-mail.
4	A. Well, these were sent to Pete Miller as	4	And there are copies, exact copies of
5	two separate documents. It may be that he combined	5	this flash drive, two made, if you need to verify
6	it. He asked me to separate them. I actually started	6	that.
7	with an assessment of the pharmacovigilance system, an	7	BY MR. DEAN:
8	assessment of the risk communication.	8	Q. So I want to get back to what you did to
9		9	prepare for the deposition besides read read what
	He asked me to combine them all, the	10	we've marked as Exhibit 50, or the first 11 pages of
10	opinions, as a conclusion.	11	Exhibit 50.
11	Then he said, this is too long. We want	12	A. Well, actually, it was it was the
12	to take out this supporting document where I	13	great deal of this. I didn't read all the verbatim
13	documented verbatim things from the FDA inspections	1	
14	and my comments that served as the basis for the	14	quotes. I went mostly through my comments in this
15	opinion.	15	document. But, no, I did not go back to the original
16	And this short document became the	16	binders yesterday.
17	opinion and this longer document became the supporting	17	Q. Okay.
18	evidence.	18	A. I only went through the original binders
19	He may have, in the process of	19	to extrapolate this, because I anticipated that this
20	submitting it electronically, been forced to recombine	20	would ground my statements very carefully. The
21	them so that they were in this order.	21	what actually happened over the course of several
22	Q. Just so we're just so the record is	22	years at this company is somewhat complex.
23	clear	23	And in the course of preparing this
24	MR. THOMPSON: Yeah. Let's	24	document, I laid out a timeline of events and the
25	BY MR. DEAN:	25	observations of the inspectors.
	Da 11	1	_ 10
	Page 11		Page 13
1	_	1	Because most of what I was presented was
1 2	Q. Could you look at could you, yourself	1 2	
	Q. Could you look at could you,	1	Because most of what I was presented was
2	Q. Could you look at could you, yourself MR. THOMPSON: Yeah, could I let me	2	Because most of what I was presented was the 483s and the Establishment Inspection Reports were
2	Q. Could you look at could you, yourself MR. THOMPSON: Yeah, could I let me just make a short statement, and that is, everything	2 3	Because most of what I was presented was the 483s and the Establishment Inspection Reports were the paucity of what you might call primary.
2 3 4	Q. Could you look at could you, yourself MR. THOMPSON: Yeah, could I let me just make a short statement, and that is, everything Dr. Frank has said is true and accurate.	2 3 4	Because most of what I was presented was the 483s and the Establishment Inspection Reports were the paucity of what you might call primary.  MR. THOMPSON: Doctor, let me do some
2 3 4 5 6	Q. Could you look at could you, yourself MR. THOMPSON: Yeah, could I let me just make a short statement, and that is, everything Dr. Frank has said is true and accurate. Everything you said is true and	2 3 4 5	Because most of what I was presented was the 483s and the Establishment Inspection Reports were the paucity of what you might call primary.  MR. THOMPSON: Doctor, let me do some impermissible coaching, and that is, if I thought that
2 3 4 5	Q. Could you look at could you, yourself MR. THOMPSON: Yeah, could I let me just make a short statement, and that is, everything Dr. Frank has said is true and accurate. Everything you said is true and accurate. That she submitted a the lengthy	2 3 4 5 6	Because most of what I was presented was the 483s and the Establishment Inspection Reports were the paucity of what you might call primary.  MR. THOMPSON: Doctor, let me do some impermissible coaching, and that is, if I thought that it would shorten the deposition, I would let you go
2 3 4 5 6 7 8	Q. Could you look at could you, yourself MR. THOMPSON: Yeah, could I let me just make a short statement, and that is, everything Dr. Frank has said is true and accurate. Everything you said is true and accurate. That she submitted a the lengthy document.	2 3 4 5 6 7	Because most of what I was presented was the 483s and the Establishment Inspection Reports were the paucity of what you might call primary.  MR. THOMPSON: Doctor, let me do some impermissible coaching, and that is, if I thought that it would shorten the deposition, I would let you go forward with those explanations.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Could you look at could you, yourself MR. THOMPSON: Yeah, could I let me just make a short statement, and that is, everything Dr. Frank has said is true and accurate. Everything you said is true and accurate. That she submitted a the lengthy document. We determined and we believe that for the ease of having a report and a supplement, that the thing to do would be to have it as a separate with a supplement. But in terms of the report, the connection or disconnection is irrelevant. And so what you have, I believe, is what Dr. Frank has as the report with, immediately following it, this lengthy discussion item by item as sort of a supplement or a supporting information. So I think that it's tempest in a teapot. In Dr. Frank's mind, she separated them. In submission, they were submitted MR. DEAN: Together.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Because most of what I was presented was the 483s and the Establishment Inspection Reports were the paucity of what you might call primary.  MR. THOMPSON: Doctor, let me do some impermissible coaching, and that is, if I thought that it would shorten the deposition, I would let you go forward with those explanations.  But I'm afraid that we're going to get back to that  MR. DEAN: Right.  MR. THOMPSON: over the course of the day.  THE WITNESS: Okay.  MR. THOMPSON: Right now, I think what he wants to know is simply what was done to prepare for this deposition, and he probably wants to know about our meeting last night and our meeting this morning.  THE WITNESS: Okay.  MR. THOMPSON: And the review of the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Could you look at could you, yourself MR. THOMPSON: Yeah, could I let me just make a short statement, and that is, everything Dr. Frank has said is true and accurate. Everything you said is true and accurate. That she submitted a the lengthy document. We determined and we believe that for the ease of having a report and a supplement, that the thing to do would be to have it as a separate with a supplement. But in terms of the report, the connection or disconnection is irrelevant. And so what you have, I believe, is what Dr. Frank has as the report with, immediately following it, this lengthy discussion item by item as sort of a supplement or a supporting information. So I think that it's tempest in a teapot. In Dr. Frank's mind, she separated them. In submission, they were submitted MR. DEAN: Together.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Because most of what I was presented was the 483s and the Establishment Inspection Reports were the paucity of what you might call primary.  MR. THOMPSON: Doctor, let me do some impermissible coaching, and that is, if I thought that it would shorten the deposition, I would let you go forward with those explanations.  But I'm afraid that we're going to get back to that  MR. DEAN: Right.  MR. THOMPSON: over the course of the day.  THE WITNESS: Okay.  MR. THOMPSON: Right now, I think what he wants to know is simply what was done to prepare for this deposition, and he probably wants to know about our meeting last night and our meeting this morning.  THE WITNESS: Okay.  MR. THOMPSON: And the review of the exhibit from the deposition, and I don't recall the exhibit number, but it was the FDA document, the fact

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1 THE WITNESS: Okay. I'm sorry. 1 documents that I was not sent, that there v	Page 16
	as/as
2 MR. DEAN: Thank you, Mr. Thompson. 2 suggestion that I review them last night or so	
3 BY MR. DEAN:  3 in the future to further expand the analysis.	
4 Q. Go ahead.  4 There was discussion of some gener	al FDA
5 A. Do I give him the details of the meeting 5 press releases on generic drugs and their imp	
7 And there were first com	e
8 ask a question, I'll try to have a focused question, 9 you give a focused answer.  8 general coaching in how to give appropriate 9 And I believe they were very, very careful to	
Journal and the state of the st	312.)
	this
The substant of June 1	
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20 to the plantage in the answer of	heen
The On the phone were transfer and the	
	y, mayoc
2	ne ask vou
	iic ask you
	Page 17
1 Q. And when was that? 1 THE WITNESS: Okay.	
2 A. That was last evening. 2 MR. THOMPSON: I think he has r	
3 Q. Was that within the last week, was 3 exhausted the maybe he hasn't exhausted,	but were
4 that the first time you met with any attorney  4 on the preparation for this deposition.	
5 representing the plaintiffs? 5 THE WITNESS: Okay.	
6 A. Yes. 6 BY MR. DEAN:	
7 Q. How long did that call last? 7 Q. All right. Thank you for that answ	
8 A. Approximately two hours. It was 8 which I think was responsive, but I want to	
9 intermittent. It was interrupted. It was scheduled 9 and ask you some follow-ups on specific thi	ngs tnat
10 to last from 5:30 to 7:30.	
11 I was down in the lobby at 6:30 11 You said, first of all, that they	th icouse
12 expecting Mr. Miller to meet me, and at quarter of 12 "they" being the lawyers presented you w	
13 6:00 I called him on his phone and he had expected me 13 that had come up in the depositions, by that	
14 to call him when I arrived. So we started late and I 14 I'm assuming you meant depositions that ha	ve occurred
15 believe we went about 15 minutes late. 15 in the last few days?	
16 O What subjects did you discuss? 16 A. Yes.	.i+h?
10 Q. What subjects and you discuss.	
17 A. I discussed some general opinions that I 17 Q. What issues did they present you was	HIC
17 A. I discussed some general opinions that I  18 had about the situation and some specific issues that  19 Q. What issues did they present you was the situation and some specific issues that  10 Q. What issues did they present you was the situation and some specific issues that	
17 A. I discussed some general opinions that I 18 had about the situation and some specific issues that 19 came from the evidence here. They presented me with 19 fact that the there was a repeated line of	
17 A. I discussed some general opinions that I 18 had about the situation and some specific issues that 19 came from the evidence here. They presented me with 20 the issues that had come up in the depositions.  17 Q. What issues did they present you was 18 A. The one that really struck me was 19 fact that the there was a repeated line of 20 questioning about specific information on D	igitek.
17 A. I discussed some general opinions that I 18 had about the situation and some specific issues that 19 came from the evidence here. They presented me with 20 the issues that had come up in the depositions. 21 And we talked about how I would stick to 22 And I responded to them that if you	igitek. were
A. I discussed some general opinions that I had about the situation and some specific issues that came from the evidence here. They presented me with the issues that had come up in the depositions. And we talked about how I would stick to the scope of my engagement, how I would respond if the  17 Q. What issues did they present you was A. The one that really struck me was fact that the there was a repeated line of questioning about specific information on D And I responded to them that if you to look at the volumes that I reviewed severe	igitek. were al weeks
A. I discussed some general opinions that I had about the situation and some specific issues that came from the evidence here. They presented me with the issues that had come up in the depositions.  And we talked about how I would stick to And I responded to them that if you the scope of my engagement, how I would respond if the questioning started to go outside of the scope of my  A. The one that really struck me was fact that the there was a repeated line of questioning about specific information on D and I responded to them that if you to look at the volumes that I reviewed sever ago to write this document, you will see in I	igitek. were al weeks ny notes
A. I discussed some general opinions that I had about the situation and some specific issues that came from the evidence here. They presented me with the issues that had come up in the depositions. And we talked about how I would stick to the scope of my engagement, how I would respond if the  17 Q. What issues did they present you was A. The one that really struck me was fact that the there was a repeated line of questioning about specific information on D And I responded to them that if you to look at the volumes that I reviewed severe	igitek. were al weeks ny notes

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Page 18
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       information given on the systems that allow specific
  1
                                                                 1
                                                                      you?
  2
       analysis of the subset of data on Digitek.
                                                                 2
                                                                               I need to -- I wrote notes, but I don't
                                                                         A.
  3
               And so I understood why your line of
                                                                 3
                                                                      think I have written them all down, and I don't --
  4
       questioning went in that direction, and we prepared me
                                                                 4
                                                                               Did you make notes at that meeting,
                                                                         Q.
  5
       to answer. And I think I can -- I've produced a
                                                                 5
                                                                      ma'am?
  6
       document that can -- is an accurate basis for any
                                                                 6
                                                                               Nothing -- only my to-do list for last
                                                                         A.
                                                                      night.
  7
                                                                 7
       answer to that.
                                                                 8
  8
               I don't -- I want to follow up. You
                                                                              MR. KAPLAN: Can we get a copy of that?
  9
       said they presented you with the issue that there was
                                                                 9
                                                                              MR. DEAN: Well, let me look at it
10
       not much specific information on Digitek.
                                                               10
                                                                      first. I'm not sure we want it.
11
               Could you be more specific about what
                                                               11
                                                                              MR. THOMPSON: Why don't you look at it
12
       the issue was they were talking to you about?
                                                               12
                                                                      before you say that.
13
               They didn't state that there was no
                                                               13
                                                                      BY MR. DEAN:
14
       specific issue on Digitek. They said that your line
                                                               14
                                                                         Q. For Mr. Kaplan's benefit, could you just
15
       of questioning repeatedly was to ask the witnesses do
                                                               15
                                                                      read what's on here so -- I don't think we're going to
16
       you have anything specific on Digitek.
                                                               16
                                                                      need a copy of that.
                                                                               It says, Two flash drives, check
17
               My extrapolation was my reaction to what
                                                               17
18
       I was given is that I was unable to subset out
                                                               18
                                                                      e-mail. And I don't know -- I don't know what the
19
       information on the systems specifically for Digitek.
                                                               19
20
               So when the FDA looks at noncompliance
                                                               20
                                                                              What I wanted to make sure is that I had
21
       with 15-day reporting, they have a sampling that
                                                               21
                                                                      all of the required evidence that you wanted for the
22
       includes Digitek cases and non-Digitek cases.
                                                               22
                                                                      deposition.
23
               I don't know how that extrapolates.
                                                               23
                                                                         Q.
                                                                               Now, let's -- thank you.
24
       Nobody presented me with data from the database that
                                                               24
                                                                              Now, I want to make sure you've answered
25
       shows X Digitek cases over X years, the adverse event
                                                               25
                                                                      my question, though. I just want a listing of the
                                                                                                                Page 21
                                                 Page 19
  1
                                                                 1
                                                                      issues they presented to you. You've given me one
       codes.
  2
               So I can't say that the analysis of the
                                                                 2
                                                                      issue.
  3
       databases or the systems was specific for Digitek. It
                                                                 3
                                                                              Are there any other issues?
  4
       was analysis of the Actavis systems that handled all
                                                                 4
                                                                         A.
                                                                               They talked to me about how to respond
                                                                 5
  5
                                                                      to questions that had multiple questions in one
       of the products. Nothing was specific to Digitek.
  6
               MR. THOMPSON: You know, let me just
                                                                 6
                                                                      question, to ask for it to be subdivided. They --
  7
       interrupt here. Certainly you have a right to ask
                                                                 7
                                                                               Excuse me. I'm not interested in their
  8
       questions and certainly Dr. Frank has shown that she's
                                                                 8
                                                                      instructions about how to respond to questions.
 9
                                                                 9
                                                                              What I'm interested in are simply this.
       going to be meticulously responsive.
                                                               10
10
               But if we're going to go through all
                                                                      Are there substantive issues at the beginning of the
11
       this again and you're going to ask the question that
                                                               11
                                                                      meeting that they flagged for you as issues that might
                                                                      come up in the deposition? That's all I want to know.
12
       we told her that you were probably going to ask, I'm
                                                               12
                                                                               At the moment, I can't remember any
13
       just not -- I just hate to sit through it twice.
                                                               13
                                                                         A.
      BY MR. DEAN:
                                                               14
14
                                                                      more.
                                                                               Okay. Thank you.
15
          O.
                What other issues did they present you
                                                               15
                                                                         Q.
16
                                                                              Now --
       with besides the one you just spoke to us about?
                                                               16
                I'm having trouble recalling
                                                               17
                                                                               I think -- I'm sorry I'm so nervous, but
17
                                                                      I'm -- actually, I can't remember the specifics.
       specifically. We talked a lot about my staying within
                                                               18
18
                                                               19
                                                                               You'll get more -- I know at the
19
       the scope of my engagement because --
                                                               20
                                                                      beginning this is -- you're going to be nervous.
20
               I don't need to go there. I understand
21
                                                               21
                                                                      You'll get comfortable.
       that.
                                                               22
                                                                              And if you think of those issues later,
22
              I just want to know, I'm interested in
23
       what issues they flagged for you last night. You've
                                                               23
                                                                      if they come back to you, we'll give you an
                                                               24
                                                                      opportunity.
24
       told me about one issue.
25
               Are there any others they flagged for
                                                               25
                                                                         A.
                                                                               Yes.
```

	Page 22		Page 24
1	MR. THOMPSON: I hate to I hate to	1	Q. Okay. And did you look at any
2	interrupt again, but I do believe Dr. Frank did	2	additional documents this morning?
3	mention that we read to her the FDA Generic Drug	3	A. I read these this morning.
4	Advisory.	4	Q. Read what this morning?
5	MR. DEAN: I've got the list here.	5	Oh, no. I meant I meant additional
6	MR. THOMPSON: Okay.	6	additional evidentiary documents, exhibits.
7	MR. DEAN: I'm getting there.	7	A. No.
8	MR. THOMPSON: Okay.	8	Q. Okay. So the only additional document
9	BY MR. DEAN:	9	that you looked at in the last two days was that
10	Q. The next thing you mentioned when you	10	what you referred to as a generic press release; is
11	were giving me the list of what happened last night	11	that correct?
12	was that they gave you additional documents that had	12	A. Yes. Now
13		13	O. Is that correct?
14	not been sent to you.  What documents did they give to you that	14	A. Yes. You
15		15	Q. You've answered. Okay? It was a very
	had not been sent?	16	simple question.
16 17	A. They were unable to access the server.	17	Let's let me go on and frame another
	The only way to obtain some of the documents was through the Citrix portal on his laptop, and that was	18	one for you.
18 19		19	A. Okay.
	not functioning. They were unable to download the documents and send them to me by e-mail.	20	Q. I believe in your original answer to me
20	· · · · · · · · · · · · · · · · · · ·	21	you mentioned that you discussed some FDA statements.
21	Your line of questioning along specific	22	Was that just the generic statement we
22	issues for Digitek brought up issues that were already	23	just spoke about?
	of concern to me.	24	A. Yes.
24 25	So a lot of what happened last night	25	A. 16s. Q. Yes?
23	was, I expressed my concerns and they responded to  Page 23		
			Page 251
1	_	1	Page 25
1 2	prepare me to address my concerns this morning.	1 2	A. I didn't see anything else in writing.
2	prepare me to address my concerns this morning.  And in coaching me to stay within the	2	<ul><li>A. I didn't see anything else in writing.</li><li>Q. Now, about three minutes ago you said</li></ul>
2 3	prepare me to address my concerns this morning.  And in coaching me to stay within the scope of my work, there were a number of documents	2	A. I didn't see anything else in writing.  Q. Now, about three minutes ago you said that this morning you expressed your concerns about
2 3 4	prepare me to address my concerns this morning.  And in coaching me to stay within the scope of my work, there were a number of documents that were not sent to me, but were sent to the other	2 3 4	A. I didn't see anything else in writing. Q. Now, about three minutes ago you said that this morning you expressed your concerns about some issues.
2 3 4 5	prepare me to address my concerns this morning.  And in coaching me to stay within the scope of my work, there were a number of documents that were not sent to me, but were sent to the other witnesses, the cardiologist who looked at the medical	2 3 4 5	<ul> <li>A. I didn't see anything else in writing.</li> <li>Q. Now, about three minutes ago you said that this morning you expressed your concerns about some issues.</li> <li>A. Well, last night and this morning.</li> </ul>
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Page 28 Page 26 we're going to hear it twice. concerned that the process of discovery was complete 1 1 and those documents were not available. 2 So it's my hope that we can -- it's my 2 3 hope that she'll tell you that we told her to tell the 3 I did not go back and do the subsequent truth at some point, but even if she doesn't -gap analysis when they sent me the second round of 4 4 5 MR. DEAN: She's left that out so far, 5 documents. 6 But in this document I prepared for Fred. 6 MR. THOMPSON: Yeah. I think we've --7 7 myself for this morning, I tried to clearly lay out what I -- what was provided to me very accurately, and 8 anyway... 8 9 BY MR. DEAN: 9 things that were not provided to me, like any of the For Mr. Thompson's sake, did 10 MHRA inspections or the responses. 10 11 Mr. Thompson tell you to tell the truth today? So my view inside Actavis, from 1992, 11 Yes. from the first consent decree, to now, is mostly 12 A. 12 13 O. Good. through the eyes of the FDA inspectors and their 13 Do you think I'm not telling the truth? 14 observations. 14 A. 15 MR. THOMPSON: No. That's a lawyer joke 15 And my opinions can only be based on between the two of us. I apologize. 16 what I actually saw or read. These are secondary 16 17 THE WITNESS: I have a concern that the 17 sources. complexity of this -- I've been involved with 18 18 I haven't seen the primary sources. I companies that have had implosions like this, and in haven't seen any individual MedWatch forms. I haven't 19 19 trying to correct it inside the company, the 20 20 seen any PSURs. I have not seen the company internal exhaustion that occurs in trying to sort out what 21 21 happened and what needs to be corrected, how to 22 document that was provided to Dr. Leikin at the time 22 23 of his Health Hazard Assessment. I have not seen the 23 correct it and document the correction can be prohibitive. 24 24 Ouality System Improvement Plan. I have not seen any And in trying to sort out what really 25 CAPAs, any CAPA trackers. 25 Page 29 Page 27 happened here very, very accurately, I don't want to MR. KAPLAN: Any what? 1 1 2 come in and make general statements that sound like THE WITNESS: CAPA trackers. When 2 companies have CAPAs, they usually track their 3 opinions. ,3 There's -- there's a lot of evidence 4 4 compliance with the CAPAs with some sort of a tool. here as to what happened, what was not reported, what 5 Some are more robust than others. Some can be as 5 6 the inspectors found, what the companies promised to 6 simple as an Excel spreadsheet. 7 do, what they did do in the remediation. 7 But if they have an inspection and 8 But there's white space that I have not they're anticipating a repeat two-year inspection, 8 9 seen. It's not -- it may or may not be in the process 9 they're documenting their remediation program on the original inspection and what are their vulnerabilities 10 of discovery. It may have been that in limiting the 10 11 scope of my opinion it was not provided to me, it was 11 for the repeat inspection. 12 If they're working with a consulting 12 provided to someone else. 13 BY MR. DEAN: firm on business processes, they usually provide this 13 information to the consulting firm for the business Okay. Let me hand you what I have 14 Q. 14 marked as Exhibit 90. analysts and the modelers to use in assisting them in 15 15 MR. DEAN: Fred. Harvey. 16 building more robust business processes and improving 16 BY MR. DEAN: 17 17 their compliance. Exhibit 90 is a Notice for this 18 18 MR. THOMPSON: Let me -- here again, let deposition asking you to bring certain documents with me -- this is not even an objection, is if I thought 19 19 20 you. 20 that this was actually covering this information for 21 Have you seen this before? the whole day, I would allow Dr. -- I would say go, 21 22 Yes. I went over this with them last A. 22 continue, Dr. Frank. She's clearly trying her best to give 23 night. 23 24 Okay. Let's go through it. full and responsive answers, but I'm concerned that O. 24 we're going to just repeat this same material and Item number one, we already have your 25 25

	Page 30		Page 32
1.	curriculum vitae.	1	Q. Excuse me. Which notebooks would it
2	Item number two was correspondence	2	summarize, Dr. Frank?
3	between you and any attorney acting on behalf of the	3	A. I think the first two that were sent to
4	plaintiffs in the Digitek litigation.	4	me.
5	Did you bring that with you?	5	Q. So and which would those be?
6	A. I have everything. I asked specifically	6	A. Okay. That would be that one there
7	twice whether I was to print e-mails. I was told no.	7	(indicating).
8	I do not have any e-mails corresponding to the case.	8	Q. Okay.
9	I asked them not to send any documents	9	A. And I specifically did not take time to
10	by e-mail. Everything was sent by FedEx either in	10	categorize this. I called them and said, I don't have
11	paper or electronic format.	11	all the documents electronically for which I want to
12	Q. And did you bring items responsive to	12	write this document. But I did not take the time to
13	number two with you today?	13	verify those disks against the binders.
14	A. Yes.	14	Q. Did you
15	Q. And could I see that, please.	15	A. And there could be variation, is what
16	A. I believe that I did print some SOPs,	16	I'm saying.
17	but I did not make comments on them. So what I know	17	Q. I want to move through this as quickly
18	about document retention, I didn't alter the paper	18	as we can.
19	copy, and there is an electronic copy. It's	19	But what I'm interested in is what you
20	equivalent.	20	were what you were provided and then what you asked
21	So I don't think I have all of the SOPs	21	for, is in follow-up, is all of that here in front
22	that I printed, but I have the electronic equivalents	22	of us now?
23	and there were no marks made on these.	23	A. Yes.
24	Q. Dr. Frank, you have given me four	24	Q. Is there anything that's responsive
25	notebooks, some loose pages of paper and two CDs;	25	strike that.
	Page 31		Page 33
1	correct?	1	Is there anything else you brought with
2	A. Yes.	2	you today other than what we have on the table?
3	Q. What is on the CDs?	3	A. No. The directions to the hotel last
4	A. As many of the documents in these	4	night and my Notice.
5	notebooks and that stack as were available	5	Q. Those I don't need.
6	electronically.	6	A. And this you have in electronic format,
7	Q. Okay. So these, the CDs, would not	7	all of this.
8	comprise everything that's in hard copy here?	8	MR. THOMPSON: Let me interrupt. She
9	<ul> <li>A. No. And I went back and asked, and I</li> </ul>	9	brought these two thumb drives, which are two copies
10	don't think all of them were available	10	of the same thing. Maybe she needs to summarize
11	electronically. There were some that were to be	11	what's on the thumb drives.
12	delivered.	12	MR. DEAN: Yes. Thank you, Fred.
13	That see that sheet there? That is	13	BY MR. DEAN:
14	the listing of at least one of the CDs. And the	14	Q. Could you do that, please?
15	checks, I don't recall having received electronically	15	A. When I started the review, the
16	the two documents there.	16	consulting firm that I worked for had me talk to
	Q. Well, if I was interested I'm not	17	somebody else who was doing expert witness work. And he said that he did individual reports of every
17		18	document he reviewed. So I started that.
18	interested in hauling all this paper with me, but	10	
18 19	or having it marked as exhibits if I can avoid it.	19	
18 19 20	or having it marked as exhibits if I can avoid it.  There's a document here that says	20	But you will not find a whole lot of
18 19 20 21	or having it marked as exhibits if I can avoid it.  There's a document here that says  Documents sent to Karen Frank; correct?	20 21	But you will not find a whole lot of comments expressed in those documents because I held
18 19 20 21 22	or having it marked as exhibits if I can avoid it.  There's a document here that says  Documents sent to Karen Frank; correct?  A. Yes.	20 21 22	But you will not find a whole lot of comments expressed in those documents because I held back very carefully. So there weren't frivolous
18 19 20 21 22 23	or having it marked as exhibits if I can avoid it.  There's a document here that says  Documents sent to Karen Frank; correct?  A. Yes.  Q. Does it does this summarize some of	20 21 22 23	But you will not find a whole lot of comments expressed in those documents because I held back very carefully. So there weren't frivolous comments made. Become what I did was
18 19 20 21 22	or having it marked as exhibits if I can avoid it.  There's a document here that says  Documents sent to Karen Frank; correct?  A. Yes.	20 21 22	But you will not find a whole lot of comments expressed in those documents because I held back very carefully. So there weren't frivolous

Videotaped

	Page 34		Page 36
1	A. Those draft documents are here.	1	correspondence and communication, were there are
2	Then what I did is, I became concerned	2	there letters in here?
3	about the complexity of what had happened and the	3	A. No.
4	amount of white space, and I started putting my own	4	Q. So did you did you ever exchange
5	document together that is as close as I can track to	5	letters with one of the plaintiffs' lawyers?
6	verbatim quotes from the FDA inspections and the	6	A. I received cover letters for each of
7	documents that I received.	7	these binders that I did not retain.
8	And after I put that together, I started	8	Q. So the cover letter would have it
9	going back and making substantive comments on that.	9.	would have just had a listing of what was in the in
10	And from the substantive comments, I drew the	10	the materials; is that right?
11	conclusions.	11	A. It didn't even have a listing. It
12	It was a step-wise process that involved	12	looked like their generic cover letter.
13	stopping the individual reports on the individual	13	Q. Enclosed please find?
14	documents.	14	A. Yeah.
15		15	Q. Okay. All right.
16	That became out of scope, unauthorized work, and it was rolled into one review document with	16	A. And the other thing that may be missing
17	*	17	is, when I when they they coached me through the
18	substantive comments and the conclusion.	18	preparation of a nice document for you. Not for a
	Q. Let's go back to Exhibit 90, please.	19	client that's in trouble that needs to remediate.
19	MR. THOMPSON: I think what she was	20	· · · · · · · · · · · · · · · · · · ·
20	saying was that the various draft iterations of the	21	So there may be a few phone calls where
21	final document		I had a pad in my hand and I scribbled notes to
22	THE WITNESS: Right.	22	myself. They were translated into this. Those notes
23	MR. THOMPSON: are contained on the	23	probably
24	thumb drive.	24	Q. Translated into what, ma'am?
25	Is that right?	25	A. The documents that they were part of.
	Page 35		Page 37
1	Page 35 THE WITNESS: Yes.	1	Q. Would they if you took notes, would
1 2		1 2	
	THE WITNESS: Yes.		Q. Would they if you took notes, would
2	THE WITNESS: Yes. MR. THOMPSON: Okay.	2	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in
2 3	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process,	2 3	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?
2 3 4	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to	2 3 4	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are.
2 3 4 5	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.	2 3 4 5	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are. Q. Okay.
2 3 4 5 6	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to	2 3 4 5 6	<ul> <li>Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?</li> <li>A. Some of them are.</li> <li>Q. Okay.</li> <li>A. There may be there may be stray notes</li> </ul>
2 3 4 5 6 7	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have	2 3 4 5 6 7	<ul> <li>Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?</li> <li>A. Some of them are.</li> <li>Q. Okay.</li> <li>A. There may be there may be stray notes that were lost.</li> </ul>
2 3 4 5 6 7 8	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have comments, they won't be substantive. They were very,	2 3 4 5 6 7 8	<ul> <li>Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?</li> <li>A. Some of them are.</li> <li>Q. Okay.</li> <li>A. There may be there may be stray notes that were lost.</li> <li>Q. Would it be would it be fair for me</li> </ul>
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2 3 4 5 6 7 8 9	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have comments, they won't be substantive. They were very, very lightweight comments.  The heavy comments were, for the most	2 3 4 5 6 7 8 9	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are. Q. Okay. A. There may be there may be stray notes that were lost. Q. Would it be would it be fair for me to assume that if there are such notes, they would be in this stack of paper right here?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have comments, they won't be substantive. They were very, very lightweight comments.  The heavy comments were, for the most part, restricted to this document and very carefully tracked to the verbatim evidence.  MR. THOMPSON: Okay.  BY MR. DEAN:  Q. What I'm thank you.  What I'm trying to get at now and I appreciate your answer. What I'm trying to get at now	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are. Q. Okay. A. There may be there may be stray notes that were lost. Q. Would it be would it be fair for me to assume that if there are such notes, they would be in this stack of paper right here? A. Yes. Q. Could you could you A. The the Q. Well, hang on. I can make it even easier.  Because Plaintiff's Exhibit 91 is in here; correct?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have comments, they won't be substantive. They were very, very lightweight comments.  The heavy comments were, for the most part, restricted to this document and very carefully tracked to the verbatim evidence.  MR. THOMPSON: Okay.  BY MR. DEAN:  Q. What I'm thank you.  What I'm trying to get at now and I appreciate your answer. What I'm trying to get at now is the documents that are called for in the in the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are. Q. Okay. A. There may be there may be stray notes that were lost. Q. Would it be would it be fair for me to assume that if there are such notes, they would be in this stack of paper right here? A. Yes. Q. Could you could you A. The the Q. Well, hang on. I can make it even easier.  Because Plaintiff's Exhibit 91 is in here; correct? A. Yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have comments, they won't be substantive. They were very, very lightweight comments.  The heavy comments were, for the most part, restricted to this document and very carefully tracked to the verbatim evidence.  MR. THOMPSON: Okay.  BY MR. DEAN:  Q. What I'm thank you.  What I'm trying to get at now and I appreciate your answer. What I'm trying to get at now is the documents that are called for in the in the Notice, which is Exhibit Number 90.  And so all the correspondence and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are. Q. Okay. A. There may be there may be stray notes that were lost. Q. Would it be would it be fair for me to assume that if there are such notes, they would be in this stack of paper right here? A. Yes. Q. Could you could you A. The the Q. Well, hang on. I can make it even easier.  Because Plaintiff's Exhibit 91 is in here; correct? A. Yes. Q. So A. I can tell you what I think is missing.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have comments, they won't be substantive. They were very, very lightweight comments.  The heavy comments were, for the most part, restricted to this document and very carefully tracked to the verbatim evidence.  MR. THOMPSON: Okay.  BY MR. DEAN:  Q. What I'm thank you.  What I'm trying to get at now and I appreciate your answer. What I'm trying to get at now is the documents that are called for in the in the Notice, which is Exhibit Number 90.  And so all the correspondence and communications you would have would be in what we have	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are. Q. Okay. A. There may be there may be stray notes that were lost. Q. Would it be would it be fair for me to assume that if there are such notes, they would be in this stack of paper right here? A. Yes. Q. Could you could you A. The the Q. Well, hang on. I can make it even easier.  Because Plaintiff's Exhibit 91 is in here; correct? A. Yes. Q. So A. I can tell you what I think is missing. Q. Well, let's stay on let's stay on
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have comments, they won't be substantive. They were very, very lightweight comments.  The heavy comments were, for the most part, restricted to this document and very carefully tracked to the verbatim evidence.  MR. THOMPSON: Okay.  BY MR. DEAN:  Q. What I'm thank you.  What I'm trying to get at now and I appreciate your answer. What I'm trying to get at now is the documents that are called for in the in the Notice, which is Exhibit Number 90.  And so all the correspondence and communications you would have would be in what we have in front of us right now; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are. Q. Okay. A. There may be there may be stray notes that were lost. Q. Would it be would it be fair for me to assume that if there are such notes, they would be in this stack of paper right here? A. Yes. Q. Could you could you A. The the Q. Well, hang on. I can make it even easier.  Because Plaintiff's Exhibit 91 is in here; correct? A. Yes. Q. So A. I can tell you what I think is missing. Q. Well, let's stay on let's stay on task here.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	THE WITNESS: Yes.  MR. THOMPSON: Okay.  THE WITNESS: This whole process, including the truncated short reports.  MR. THOMPSON: Okay.  THE WITNESS: Which you're welcome to review, which should not have they will have comments, they won't be substantive. They were very, very lightweight comments.  The heavy comments were, for the most part, restricted to this document and very carefully tracked to the verbatim evidence.  MR. THOMPSON: Okay.  BY MR. DEAN:  Q. What I'm thank you.  What I'm trying to get at now and I appreciate your answer. What I'm trying to get at now is the documents that are called for in the in the Notice, which is Exhibit Number 90.  And so all the correspondence and communications you would have would be in what we have in front of us right now; correct?  Would be somewhere in here; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Would they if you took notes, would they be on a piece of paper that would be somewhere in the stack in front of us?  A. Some of them are. Q. Okay. A. There may be there may be stray notes that were lost. Q. Would it be would it be fair for me to assume that if there are such notes, they would be in this stack of paper right here? A. Yes. Q. Could you could you A. The the Q. Well, hang on. I can make it even easier.  Because Plaintiff's Exhibit 91 is in here; correct? A. Yes. Q. So A. I can tell you what I think is missing. Q. Well, let's stay on let's stay on task here. A. Okay.

Videotaped

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1	correspondence between you and the plaintiffs'	1	deposition and the exhibits to her deposition;
2	lawyers?	2	correct?
3	A. Nothing of substance.	3	A. Yes.
4	Q. Is there anything? In what we have	4	Q. So we're going to get that one off the
5	here, is there any correspondence?	5	table.
6	A. No. They're only documents. The	6	A. Now, that had
7	letters were all these generic cover letters.	7	Q. Now, you said "that," we have two
8	Q. All right. Fine.	8	notebooks. Let me which one did you want to refer
9	Then number three, it says, all other	9	to, Dr. Frank?
10	documents prepared by attorneys for the plaintiff and	10	A. The one where I removed the cover sheet,
11	sent to the witness.	11	which I should not have done. I apologize.
12	Would they all be in front of us here?	12	Q. So this is the smaller notebook you were
13	A. Can you repeat the question?	13	talking about?
14	Q. Yes. I'm on number three, Dr. Frank.	14	A. It's the later. The one where I removed
15	We asked you to bring all other	15	the cover was the first. There were cover sheets,
16	documents prepared by attorneys for the plaintiffs and	16	similar cover sheets.
17	sent to the witness.	17	Q. I have two notebooks. They each do have
18	Would they all be in front of us?	18	a Table of Contents; correct?
19	A. Yes.	19	A. Yes. Yes.
20	<ul> <li>Q. Okay. It says, all documents including</li> </ul>	20	Q. And did these both come at the same time
21	documents and deposition transcripts which you have	21	or did they come at different times?
22	received from any source.	22	A. Came at different times.
23	Now, you didn't are the if I	23	Q. Which one came first, Dr. Frank?
24	remember right, you reviewed the deposition of Sarita	24	A. The one where I removed the cover.
25	Thapar and Misbah Sherwani; correct?	25	Q. Is that the larger one, the larger
	Page 39		Page 41
1	A. Yes. They're in these binders.	1	notebook?
2	Q. Okay. Do you	2	And this notebook
3	A. May I ask a question?	3	MR. KAPLAN: You have to say yes or no.
4	Q. Do you know in a minute.	4	THE WITNESS: Yes.
. 5	Do you know which binder they're in,	5	BY MR. DEAN:
6	Dr. Frank?	6	Q. It may not be relevant for our purposes
7	A. Right here and here (indicating).	7	later on, but this notebook has no markings on the
8	Q. Well, we're making progress, Dr. Frank.	8	outside. But it does have a Table of Contents on the
9	One of these notebooks, which says 1 of	9	inside, which we will which we will mark as an
10	1	10	exhibit.
11	A. Yeah.	11	MR. DEAN: And can you just give me an
12	Q contains the deposition of Misbah	12	arbitrary exhibit number? Should we do something,
13	Sherwani and all of her exhibits to her deposition;	13	start at call it 250, do you think?
14	correct?	14	MS. TAKLA: Sure.
15	A. Uh-huh.	15	MR. DEAN: Why don't we we will mark
16	Q. Is that right? Yes?	16	this later as Exhibit 250 so we don't have to go off
17	A. Yes.	17	camera right now.
18	Q. So we're going to get that notebook off	18	Make a note of that, please.
19	the table. I'll put it back over with your material	19	BY MR. DEAN:
20	later. I just don't want to unhook from my	20	Q. This notebook says, Digitek Expert Table
1 7 7	A. Yes.	21	of Contents. It has 18 items; correct?  A. Yes.
21			/) VAC
22	Q. And then another notebook, which says 1	22	
22 23	Q. And then another notebook, which says 1 of 1, says Deposition of Sarita Thapar; correct?	23	Q. Okay. And when and this was the
22	Q. And then another notebook, which says 1	ı	

	Page 42		Page 44
1	Q. Do you recall approximately when you	1	Miller and Megan Carter at the Philadelphia Airport at
2	received this notebook?	2	either 12 o'clock or 1:00 p.m.
3	A. Sometime in the beginning of May.	3	Q. Doesn't matter what time you met.
4	Q. And then what is the second, smaller	4	So that's the day you requested these
5	notebook?	5	documents; is that right?
6	A. That contains some of the additional	6	A. Yes.
7	documents that I requested.	7	Q. Now, when you requested, did you did
8	Q. So this has a document this has a	8	you hand them a list? Did you give them did you
9	Table of Contents that has 11 items; correct?	9	send them an e-mail?
10	A. May I say something?	10	How did you convey the information to
11	Q. Of course.	11	them?
12	A. I'm actually concerned that there's one	12	A. I had made a list for myself, and I
13	more binder. But I moved these to the side of the	13	believe that list is in here.
14	office and stacked them specifically several weeks	14	Q. Okay. And then how shortly after that
15	ago.	15	meeting did you receive the smaller notebook?
16	There's a problem in that I cleaned out	16	A. It took a while. I think they were sent
17	my closet with all of my old binders from my	17	by FedEx ground, rather than FedEx overnight, because
18	fellowship at the FDA, and I can't imagine that I	18	I called them twice concerned that there was a delay.
19	mixed these binders in the stack with my old binders	19	MR. DEAN: Actually, you have exhibit
20	at the FDA, but I need to make you aware of that.	20	stickers I see, don't you?
21	Because I recall that I got more	21	Why don't you go ahead and we'll is
22	binders, and	22	it all right if I mark the original with the exhibit
23	Q. I'm sorry, you said you recall you got	23	sticker?
24	more binders?	24	MR. THOMPSON: That's fine with me. I
25	I want to make sure I heard you	25	don't know the terms with this law firm. Can we make
	Page 43		Page 45
1	correctly. Did you say more?	1	a copy here?
2	A. I'm trying to remember whether there was	2	MR. DEAN: Yes. We can get copies. I
3	a fifth binder and I'm a little bit embarrassed.	3	just want to get it marked so that
4	Q. Well	4	MR. THOMPSON: Yes, that would be
5	MR. THOMPSON: Let me say	5	that's actually a good idea.
6	BY MR. DEAN:	6	MR. DEAN: Yes. If you'll give me an
. 7	Q. We'll come let me let me finish	7	exhibit sticker, I'll go ahead and mark this so we
8	the questioning on this and we'll come back to that.	8	don't get confused later on.
9	Okay.	9	(Exhibits D-250 and D-251 were marked
10	So this one that says it has 11	10	for identification.)
11	items, and we're going to mark this as Number 251, the	11	BY MR. DEAN:
12	Table of Contents. You said that it represents	12	Q. And, Dr. Frank, we'll get copies for
13	documents that you requested; is that correct?	13	everyone later. But the larger notebook, the Table of
14	A. Yes.	14	Contents, I've marked as Exhibit 250.
15	Q. Okay. And when did you make the when	15	Do you see that?
16	did you make that request?	16	A. Yeah.
17	A. At a lunch meeting with Pete Miller, and	17	Q. And that was the one you received
18	I can check the date in my date book. Do you need the	18	initially; correct?
19	exact date?	19	A. Yes, in its entirety.
20	Q. Well, I would like to get an approximate	20	Q. And then Exhibit 251 is the notebook you
21	yes, I would like yes, I would like to know when	21	received after your meeting with Mr. Miller and
22	you made the request. Yes.	22	Ms. Johnson; right?
23	If you've got a note on that, rather	23	A. Yeah.
	•		
24	than guesstimating, that would be good.	24	Q. And then you said, I think you were just
	than guesstimating, that would be good.  A. It was Wednesday, June 2nd. I met Pete	24 25	Q. And then you said, I think you were just telling me, that somewhere in this other stack of

Videotaped

June 30, 2010

### Page 46 Page 48 BY MR. DEAN: 1 papers would be a list where you request -- you made 1 2 All right. Let me hand you first what I 2 the request for follow-up documents; is that right? 3 Could you look and see if you could find 3 marked as Number 252. 4 Could you tell us what that is, please. 4 that for me. 5 5 A. These were the documents where I started A. 6 listing what I did and did not have to review and 6 These were notes to myself --7 7 Q. Please keep your voice up, too. tried to define what you might call the white space in 8 8 These were notes to myself as I tried to the dossiers. They're not --A. 9 O. First of all, let me pause here. Let's 9 define what was sent to me as far as the sequential 10 FDA Establishment Inspection Reports, warning letters, 10 stay on the question. Is there a document either which you 11 the company responses and CAPAs, so that I was 11 12 handed to me or that you still have with you that 12 defining what I was going to be basing my opinions on. 13 Is that kind of a summary of the -- not 13 represents a listing of the documents that are in the 14 of every document, but the kinds of material that you 14 smaller notebook? 15 A. No. I did not request those 15 had received? Well, I got frustrated and concerned 16 16 specifically. I talked to them about my concerns about what I called the white space or the absent 17 that I was being asked to render an opinion on what 17 happened in a company, and I had only selected 18 documents in what I was sent, and they made the 18 19 decision what additional documents to send me. 19 documents over the period. 20 So I don't have the -- a lot of company 20 Okay. So then what is represented in 21 the smaller notebook that's got Exhibit Number, on the 21 responses and CAPAs. I don't know many things about 22 Table of Contents, 251, is a selection of documents 22 the adequacy of their remediation plans. And then I actually -- this is a 23 that Mr. Miller and Ms. Johnson sent to you after 23 24 24 preliminary list. I didn't expect to give it to you. hearing general concerns about white space; correct? 25 Yes. But I --25 But I then started to sort out when I did this in my Page 47 Page 49 1 You -- just so we're clear, you did not 1 comment document, the company's responses. O. 2 2 How many letters went back and forth to give them this list? 3 They made this selection based upon what 3 -- between the health authorities and the company and 4 you -- some concerns you had expressed; is that fair? 4 what were the comments, the substantive issues in 5 5 A. Yes. those. 6 I did not go from here to here and say, 6 Q. Okay. 7 oh, I found this warning letter. There could be 7 About those lists that I started to --A. 8 inaccuracies in this. This was my preliminary list. 8 Q. Hang on. I'll get to these. Okay? 9 9 Q. Could I just see that briefly, please. A. Okay. 10 We're just going to try to -- I'll try 10 A. (Witness complies.) 11 to ask a focused question, you try and give me an 11 O. Could you tell me briefly what 253 is. This -- these are notes that I took in 12 answer and stop, and then I'll ask you another 12 13 writing the very early individual reports. And there 13 question. Okay? 14 A. Okay. 14 are a lot of very close notes or verbatim transcripts 15 of the documents as I went through them in 15 All right. Now, you have handed to Q. 16 excruciating detail. 16 me -- from the loose documents, you've handed to me 17 And then what I wanted -- what I should 17 looks like three different documents; is that correct? have done is asked for them up front electronically. 18 Uh-huh. 18 A. 19 But this became the basis of this report here. 19 O. Yes? 20 So Exhibit 253 is a document you used 20 A. These were prepared -when you were writing what we marked as Exhibit 50; 21 Hold on. 21 22 22 MR. DEAN: Let me mark these so we're correct? This could be considered an early draft 23 clear so we don't get --23 A. 24 of Exhibit 50. 24 (Exhibits D-252 through D-254 were 25 marked for identification.) 25 Okay. Very good. Thank you.

13 (Pages 46 to 49)

Videotaped

	Page 50	·	Page 52
1 .	And for the record, what is 254?	1	A. Yes.
2	A. More notes to myself.	2	Q. Okay. Let me go back to my question
3	Q. Do you remember what what do they	3	because my question I think was focused. I think
4	generally represent?	4	you've come close to answering it.
5	A. I believe these are my notes from the	5	But did you give a specific list of
6	meeting with Mr. Miller and Ms. Carter on June 2nd.	6	documents to Mr. Miller to fill which, in your
7	Q. Could you read for me this particular	7	mind, would fill out what you are calling the white
8	entry, it starts out documents, I think. And you	8	space that you wanted to be provided?
9	write pretty well, but I'm just having trouble reading	9	A. I think I had the list in front of me
10	that.	10	and I read down it. I may have translated a few of
11	A. Well, this is not that good. I wish	11	those to another paper, but he responded to my going
12	that if I had known that these were going to be	12	down the list what was and was not available at that
13	given to you, I would have notated them much more	13	point in discovery.
14	carefully.	14	The fact that discovery was complete and
15	Q. Just try to, as best you can, read that	15	then there was discussion of there may be another
16	one sentence for me.	16	round of discovery and the possibility of obtaining
17	A. It says, preponderance of the evidence,	17	those documents.
18	civil.	18	But I did not type up a list or write up
19	Q. Excuse me.	19	a specific list that I handed to him. And I can't
20	A. Right above that?	20	recall the specifics of the exchange. A lot of this
21	Q. Yes. That one right there.	21	was my asking questions of them.
22	A. Document for withholding.	22	How do I prepare these documents for
23	Q. Do you know what thought you were trying	23	expert witness and can I get any of these?
24	to capture there? And if you don't, just tell me.	24	I would have these if I was an FDA
25	A. I think it's the time that I decided	25	medical officer. I would have some of this
25	Page 51	<u> </u>	Page 53
1	this may have been to myself that this situation	1	information if I was inside the company and helping
2	this may have been to myself that this situation was so convoluted, I wanted a document that would	2	information if I was inside the company and helping with the remediation.
2 3	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information	2	information if I was inside the company and helping with the remediation.  Can you get this for me now so my
2 3 4	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.	2 3 4	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete
2 3 4 5	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and	2 3 4 5	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?
2 3 4 5 6	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and the complexity of what happened in the company, the	2 3 4 5 6	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?  Q. Can we agree, then, that you never gave
2 3 4 5 6 7	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and the complexity of what happened in the company, the intermittent evidence that was presented, the fact	2 3 4 5 6 7	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?  Q. Can we agree, then, that you never gave Mr. Miller or any plaintiff's lawyer a specific list
2 3 4 5 6 7 8	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and the complexity of what happened in the company, the intermittent evidence that was presented, the fact that there's things that I would have liked to have	2 3 4 5 6 7 8	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?  Q. Can we agree, then, that you never gave Mr. Miller or any plaintiff's lawyer a specific list of documents that you wanted to look at?
2 3 4 5 6 7 8	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and the complexity of what happened in the company, the intermittent evidence that was presented, the fact that there's things that I would have liked to have seen that we couldn't obtain, that I wanted to	2 3 4 5 6 7 8 9	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?  Q. Can we agree, then, that you never gave Mr. Miller or any plaintiff's lawyer a specific list of documents that you wanted to look at?  Can we agree on that?
2 3 4 5 6 7 8 9	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and the complexity of what happened in the company, the intermittent evidence that was presented, the fact that there's things that I would have liked to have seen that we couldn't obtain, that I wanted to carefully track that for this very situation, so I	2 3 4 5 6 7 8 9	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?  Q. Can we agree, then, that you never gave Mr. Miller or any plaintiff's lawyer a specific list of documents that you wanted to look at?  Can we agree on that?  A. Yes. And next time I will very
2 3 4 5 6 7 8 9 10	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and the complexity of what happened in the company, the intermittent evidence that was presented, the fact that there's things that I would have liked to have seen that we couldn't obtain, that I wanted to carefully track that for this very situation, so I could present to you what I had, what I did not have,	2 3 4 5 6 7 8 9 10	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?  Q. Can we agree, then, that you never gave Mr. Miller or any plaintiff's lawyer a specific list of documents that you wanted to look at?  Can we agree on that?  A. Yes. And next time I will very carefully.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and the complexity of what happened in the company, the intermittent evidence that was presented, the fact that there's things that I would have liked to have seen that we couldn't obtain, that I wanted to carefully track that for this very situation, so I could present to you what I had, what I did not have, and track the opinions very, very closely to what I was able to see.  Q. Did you ever submit to the plaintiffs a listing of documents you thought you were missing that you specifically wanted them to provide to you?  A. I gave Pete Miller some notes from the meeting as I was talking in generalities. I don't remember that was if that was on the back of the list. I don't I did not type up a specific list.  I believe I showed him these.  Q. These being what? Which exhibit number?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?  Q. Can we agree, then, that you never gave Mr. Miller or any plaintiff's lawyer a specific list of documents that you wanted to look at?  Can we agree on that?  A. Yes. And next time I will very carefully.  MR. THOMPSON: Dick, I can put an exhibit right here. That's the you got that; right?  MR. DEAN: Right.  MR. THOMPSON: Okay.  (Exhibit D-255 was marked for identification.) BY MR. DEAN:  Q. I'm handing you what I've marked as
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	this may have been to myself that this situation was so convoluted, I wanted a document that would allow me to carefully track the absence of information on specific ADE's complaints or investigations.  Because of this type of situation and the complexity of what happened in the company, the intermittent evidence that was presented, the fact that there's things that I would have liked to have seen that we couldn't obtain, that I wanted to carefully track that for this very situation, so I could present to you what I had, what I did not have, and track the opinions very, very closely to what I was able to see.  Q. Did you ever submit to the plaintiffs a listing of documents you thought you were missing that you specifically wanted them to provide to you?  A. I gave Pete Miller some notes from the meeting as I was talking in generalities. I don't remember that was if that was on the back of the list. I don't I did not type up a specific list.  I believe I showed him these.  Q. These being what? Which exhibit number?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	information if I was inside the company and helping with the remediation.  Can you get this for me now so my opinion can be based on a broader and more complete compilation of the evidence?  Q. Can we agree, then, that you never gave Mr. Miller or any plaintiff's lawyer a specific list of documents that you wanted to look at?  Can we agree on that?  A. Yes. And next time I will very carefully.  MR. THOMPSON: Dick, I can put an exhibit right here. That's the you got that; right?  MR. DEAN: Right.  MR. THOMPSON: Okay.  (Exhibit D-255 was marked for identification.)  BY MR. DEAN:  Q. I'm handing you what I've marked as Defendant Exhibit 255, which is entitled Documents sent to Karen Frank, and it has 29 items listed on it.  And I see that 250 and 251, one has 18

	•		· 1
	Page 54		Page 56
1	that Exhibit 255 is simply a compilation of the Table	1	I was a little loathed to move in to
2	of Contents of these other two notebooks?	2	litigation. And this was the first time I had done
3	A. I believe so. I called their admins to	3	any expert witness work. I was not certain how to
4	ask about these, and I think about this one.	4	prepare the documents, how to format the documents.
5	Q. First of all, you	5	I prepared FDA reviews, I prepared
6	A. Yes.	6	things to go to the health authorities, but I was
7	Q. I want to give you the opportunity, but	7	asking him questions about being an expert witness and
8	do you if you need to look at it, but is 255 simply	8	trying to determine if I was going to tactfully
9	a compilation of what we have on the Table of Contents	9	decline this engagement and simply not undertake
10	on 250 and 251?	10	expert witness work.
11	A. I believe so, but I specifically did not	11	And I had discussions with Mr. Miller
12	check. I did not bill them for time verifying this	12	and with Megan Carter in sorting out, you know, how to
13	against either of those binders or against the	13	proceed with the work. So there was coaching and
14	electronic.	14	advice as I began to develop a way to develop these
15	Q. When was 250 did you prepare 255 or	15	documents.
16	did someone else?	16	I asked them for copies of Jim Farley's
17	A. Someone else did.	17	documents so I could format them appropriately. And
18	Q. Do you know who did?	18	they did not want to do that because they were in
19	A. One of the admins or paralegals at the	19	draft.
20	Miller firm.	20	So they gave me indications of how they
21	Q. Okay. Why don't you let me have that	21	wanted the documents formatted.
22	one back.	22	So what you're seeing is indication of
23	A. (Witness complies.)	23	somebody who had not previously done expert witness
24	Q. Now, you just pointed out that there's	24	work taking on assignment and being rather transparent
25	some handwriting in red ink on here. Is that your	25	with the consulting firm and the attorneys as to my
		········	Page 57
	Page 55	_	•
1	handwriting?	1	present state of experience with this and getting
2	A. No. That's from the admins at the firm.	2	advice on how to proceed.
3	Q. Okay.	3	Q. Did Smart are you working through
4	(Exhibit D-256 was marked for	4	Smart Consulting in this litigation?
5	identification.)	5	A. Yes.
6	BY MR. DEAN:	6	Q. Did they recruit you for this
7	Q. What is 256?	7	assignment?
8	A. That is my notes from a discussion with	8	A. Yes.
9	Smart Consulting about the way another expert	9	Q. Had they already recruited Mr. Farley?
10	consultant approached review of the cases.	10	A. Yes. Q. Was Smart Consulting the first company
11	Q. And that consultant would be Mr. Farley?	11	Q. Was Smart Consulting the first company that approached you about taking on this assignment?
12	A. Yes.	12 13	A. Yes.
13	Q. When is this in your handwriting?	13	Q. And when was that?
14	A. Yes.	15	A. I don't recall the date, but I do have a
15	Q. And who did you speak to?	16	signed copy of the Consulting Agreement.
16	A. On the telecon were Denise Smart, Nigel	17	Q. Is that in the documents we have here?
17	Smart, and Jim Farley.  O. And what was the occasion for the four	18	A. Yes. I scanned it with my date of
18		19	signature.
19	of you to speak to each other?  A. Remember earlier I said that I had been	20	Q. Where is it? Is it in one of
20	A. Kemember earner i said (nat i nad deeil	40	-
1 2 1		21	A You have a scanned electronic convict
21	approached about doing this kind of work in the past?	21	A. You have a scanned electronic copy of
22	approached about doing this kind of work in the past?  Q. Yes.	22	this document. That was the one that was faxed to
22 23	approached about doing this kind of work in the past?  Q. Yes.  A. Well, I had declined it. And Smart	22 23	this document. That was the one that was faxed to Smart Consulting.
22	approached about doing this kind of work in the past?  Q. Yes.	22	this document. That was the one that was faxed to

Videotaped

	Page 58		Page 60
1	MR. THOMPSON: Well, that's your	1	A. Yes.
2	original?	2	Q. Is there some reason why it was removed
3	THE WITNESS: It's my original.	3	from the notebook?
4	MR. DEAN: Well, you're going to get it	4	A. It wasn't deliberate. What I have are
5	back, just with an exhibit sticker on it. Is that	5	the loose documents in a stack and the notebooks. But
6	okay?	6	there no, there was no I did not cite that or
7	THE WITNESS: Yes. Whatever you need.	7	the injunction or the consent decrees in my reports.
8	(Exhibit D-257 was marked for	8	It was reviewed initially, possibly
9	identification.)	9	reviewed twice, but I did not use it as evidence.
10	BY MR. DEAN:	10	Q. Are these separate pages or are these
11		11	one document?
12	Q. So 257 is a copy of that agreement;	12	A. They're separate.
13	correct?	13	(Exhibits D-259 and D-260 were marked
	A. Yes.	14	for identification.)
14	Q. Had you ever before this agreement,	15	BY MR. DEAN:
15	had you ever done anything with Smart Consulting?		•
16	A. I provided them with some business	16	
17	processes for a proposal in 2009 on product	17	A. I was trying to sort out what was the
18	complaints.	18	business process in the company for evaluation of out
19	I believe I was recruited to be on a	19	of spec results, product complaints.
20	proposal for another consulting assignment, and for	20	There was no evidence provided to me
21	confidentiality, I don't think I can tell you what the	21	that the work that I did in industry of doing routine
22	client was.	. 22	Health Hazard Assessments was being done, and I wasn't
23	But I did not provide any information to	23	certain whether it was just that I didn't receive the
24	Smart. They had two spots that I could possibly fit	24	documents.
25	in and there was a phone conversation as to how I	25	But when I've done work for clients
	Page 59		Page 61
	1 dgc 33		rage of
1	would fit best into that engagement.	1.	who've been inside companies and there is a
1 2		1 · 2	who've been inside companies and there is a manufacturing deviation, particularly if it's released
	would fit best into that engagement.		who've been inside companies and there is a
2	would fit best into that engagement.  And then I did some work on a REMS	2	who've been inside companies and there is a manufacturing deviation, particularly if it's released
2 3	would fit best into that engagement.  And then I did some work on a REMS proposal for them back probably in March of 2010 where	2 3	who've been inside companies and there is a manufacturing deviation, particularly if it's released in the market, I would usually get a copy of an
2 3 4	would fit best into that engagement.  And then I did some work on a REMS proposal for them back probably in March of 2010 where we did not win the engagement.	2 3 4	who've been inside companies and there is a manufacturing deviation, particularly if it's released in the market, I would usually get a copy of an investigation where if they had a sample of the
2 3 4 5	would fit best into that engagement.  And then I did some work on a REMS proposal for them back probably in March of 2010 where we did not win the engagement.  And it was on the basis of those interactions that they approached me about being an expert witness on this case.	2 3 4 5	who've been inside companies and there is a manufacturing deviation, particularly if it's released in the market, I would usually get a copy of an investigation where if they had a sample of the product, they would bring it back in-house and do analytics.  If they needed to, they would check it
2 3 4 5 6	would fit best into that engagement.  And then I did some work on a REMS proposal for them back probably in March of 2010 where we did not win the engagement.  And it was on the basis of those interactions that they approached me about being an	2 3 4 5 6	who've been inside companies and there is a manufacturing deviation, particularly if it's released in the market, I would usually get a copy of an investigation where if they had a sample of the product, they would bring it back in-house and do analytics.
2 3 4 5 6 7	would fit best into that engagement.  And then I did some work on a REMS proposal for them back probably in March of 2010 where we did not win the engagement.  And it was on the basis of those interactions that they approached me about being an expert witness on this case.	2 3 4 5 6 7	who've been inside companies and there is a manufacturing deviation, particularly if it's released in the market, I would usually get a copy of an investigation where if they had a sample of the product, they would bring it back in-house and do analytics.  If they needed to, they would check it
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Videotaped

	Page 62		Page 64
1	A. And	1	in the investigation of product complaints, which I've
2	Q. And did you did you make any inquiry	2	never done.
3	in this case as to whether there were product	3	I received the results to write the
4	complaint forms that you could look at and see how	4	Health Hazard Assessments. So my absence of asking
5	they were processed?	5	for them may have been my assumption of where they
6	Did you ask the plaintiffs' lawyers for	6	were to be directed.
7	that type of information?	7	MR. DEAN: Okay. Let's take a break.
8	A. Yes, I did. I commented on June 2nd on	8	Our tape needs to be changed. We'll get
9	the absence of this information, and	9	some copies of exhibits and we can all stand up and
10	Q. Let me just ask you, did the plaintiffs'	10	walk around a little bit.
11	lawyers ever provide to you any product complaints on	11	Let's go off the record.
12	Digitek?	12	THE WITNESS: Okay.
13	A. Yes. But I believe they were after the	13	VIDEO OPERATOR: Going off the video
14	recall. What I did receive was the investigation	14	record.
15	report of the double-thick tablet of Digitek. The	15	This is the end of Tape 1.
16	complaint registered by a pharmacist in Bellingham,	16	The time is 10:27 a.m.
17	Washington, in July of 2004.	17	(A recess was taken from 10:27 a.m. to
18	Q. I'll get back to that. I don't want to	18	10:43 a.m.)
19	heeding Mr. Thompson's admonition, I don't want to	19	VIDEO OPERATOR: We're now back on the
20	repeat myself.	20	video record.
21	But let me just ask you: As I	21	This is the start of Tape 2.
22	understood it, you asked for product complaints on	22	The time is 10:43 a.m.
23	Digitek before the recall, also, didn't you?	23	BY MR. DEAN:
24	A. They were not on my list. I didn't say	24	Q. Dr. Frank, I think we just have a couple
25	product complaints that I can recall specifically.	25	more documents to mark and have you identify and then
<b></b>		<b></b>	
1	Page 63		Page 65
1	Page 63	1	_
1 2	Q. So you did not so just so I'm clear,	1 2	we'll get into the substance of this.
2	Q. So you did not so just so I'm clear, you did not ask the plaintiffs' lawyers to provide	1 2 3	
2 3	Q. So you did not so just so I'm clear, you did not ask the plaintiffs' lawyers to provide product complaints on Digitek prior to the recall; is	2	we'll get into the substance of this.  I don't think I've asked you what Number
2 3 4	Q. So you did not so just so I'm clear, you did not ask the plaintiffs' lawyers to provide product complaints on Digitek prior to the recall; is that correct?	2 3	we'll get into the substance of this.  I don't think I've asked you what Number  260 is.  A. This is more notes.
2 3 4 5	Q. So you did not so just so I'm clear, you did not ask the plaintiffs' lawyers to provide product complaints on Digitek prior to the recall; is that correct?  A. I believe they were volunteered. What I	2 3 4	we'll get into the substance of this.  I don't think I've asked you what Number  260 is.  A. This is more notes.  Q. And do you know what day you took those
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. So you did not so just so I'm clear, you did not ask the plaintiffs' lawyers to provide product complaints on Digitek prior to the recall; is that correct?  A. I believe they were volunteered. What I was looking for was investigation reports of product complaints and realtime Health Hazard Assessments, which would have been generated from those product complaint reports.  Q. Did you ask for product complaints on Digitek prior to the recall? Yes or no?  A. I would have to say no, unless you would consider it implied in asking for evidence that would confirm that those business processes were in place and in use during this period.  Q. Okay. So but you didn't specifically ask for them; correct?  A. No.  Q. Okay. Fine.  A. May I?  Q. You can go ahead and say whatever you'd like to say.  A. It may be a result of my naivete, and I	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	we'll get into the substance of this.  I don't think I've asked you what Number 260 is.  A. This is more notes.  Q. And do you know what day you took those notes, what the occasion was for taking those notes?  A. I'm trying to remember whether I made them before or after the meeting with Pete Miller on the 2nd.  As I said, I was coached somewhat into how to leverage my FDA experience, my industry experience, to produce work products for attorneys as an expert witness.  And I actually started this project with my, what I'll say, my modus operandi as an FDA medical officer.  And then I started to tease out what I could about what was going on inside these companies, what business processes were in place and in use.  And I brought some of these notes to the meeting with Mr. Miller and Ms. Carter, and there were some that I made.  And I started to explain to them my

Videotaped

	Page 66		Page 68
1	documents where the FDA clearly documented things.	1	A. Yes. I said something earlier about
2	And that's the basis of this large	2	possibly having five binders. I think this was my
3	document, it's finding the answers to these questions	3	fifth. This was the last thing delivered, and
4	or any information that elucidated how are these	4	Q. By this, you are holding up Exhibit 91;
5	business processes in place. So these are my notes to	5	correct?
6	myself.	6	A. Yes. This was the last thing that Pete
7	Q. Taken at a meeting with Mr. Miller; is	7	Miller sent to me by FedEx. I'm not sure why it
8	that right?	8	wasn't in the others, but this is a very key
9	A. Or sketched at a meeting with Mr. Miller	9	inspection report to piecing together what happened
10	to say these are things that typically occur in a	10	and it was the last piece of information to arrive.
11	company and what while I'm looking at inspection	11	MR. THOMPSON: Let me see if I can
12	reports that are samplings of compliance with SOPs, I	12	satisfy the defendants with regard to the fifth
13	don't have any SOPs or work flows and I'm trying to	13	binder. My understanding is that you think there may
14	piece together what was in place and in use from the	14	be a fifth binder. You're not certain.
15	FDA reports and the warning letters.	15	If I can just simply say, we will go and
16	And that's when I asked for more	16	make a diligent search, and if we uncover a fifth
17	information to start to give myself a clearer picture.	17	binder that's been placed in another binder, we will
18	Q. Okay. You also brought with you a copy	18	make that available to the defense and we will
19	of Plaintiff's Exhibit 91, which is a 2008 IDR.	19	certainly give you an opportunity to question her
20	You also brought a in your papers was	20	either by telephone or by reconvening the deposition.
21	a February 28, 2006 letter from Amide to the FDA;	21	Is that
22	correct?	22	MR. DEAN: That's acceptable. Thank
23	A. Yes. Now	23	you.
24	Q. No, no. That's that was that's	24	MR. THOMPSON: All right.
25	you've answered the question.	25	BY MR. DEAN:
	Page 67		Page 69
1	Page 67  A. All right.	1	Page 69  Q. And as I understand it, as you sit here
1 2		1 2	
	A. All right.		Q. And as I understand it, as you sit here
2	<ul><li>A. All right.</li><li>Q. And then you brought a three-page</li></ul>	2	Q. And as I understand it, as you sit here today, you're not sure whether there was another binder or not?  A. I'm embarrassing myself that I didn't
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2 3 4	<ul> <li>A. All right.</li> <li>Q. And then you brought a three-page document, which is a Actavis document, that bears the Bates label 65400 through 65402; is that correct?</li> <li>A. Yes.</li> <li>Q. And is it fair to say that we have now</li> </ul>	2 3 4	Q. And as I understand it, as you sit here today, you're not sure whether there was another binder or not?  A. I'm embarrassing myself that I didn't keep a clear catalog. But I when I finished this report, I gathered everything up and I put it over to
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. All right. Q. And then you brought a three-page document, which is a Actavis document, that bears the Bates label 65400 through 65402; is that correct? A. Yes. Q. And is it fair to say that we have now reviewed all the documents that you brought with you today? A. Yes. Q. But? A. I believe this document may have been taken from a binder and not been appropriately reinserted because it is a punched document. Q. Correct. So that's the February 28, 2006 document. So you're suggesting it may actually go in one of the notebooks that we looked at previously; correct? A. Yes. Q. Okay. Now, is it fair to say, having gone through all of these documents, that you have brought that the items we've just gone over would	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And as I understand it, as you sit here today, you're not sure whether there was another binder or not?  A. I'm embarrassing myself that I didn't keep a clear catalog. But I when I finished this report, I gathered everything up and I put it over to the side. And I, for some reason, am really it's just bothering me.  And so I'm willing to embarrass myself and say, you know, I had this idea there were five, but, to my knowledge, everything that I used for this report is in front of us.  But I would sure appreciate to make sure that I didn't accidentally file this with something else.  MR. THOMPSON: All right.  MR. DEAN: We'll ask you to follow up on that and if you find something, and Mr. Thompson will look at his records, and if there is a fifth notebook, it's my understanding that the defendants will be informed of that.  THE WITNESS: Yes.

Page 7	0	Page 72
1 BY MR. DEAN:	1	evaluated.
2 Q. And just out of the for the sake of	2	And then when you read the conclusions,
3 caution, we have marked as Exhibit 261 the color copy	1	that would be the final. And I cannot guarantee you
of your report, and I have a copy for Mr. Thompson an		that every single comment in this document has been
5 for Mr. Kaplan because it may assist us as we proceed	5	extracted into the conclusion.
6 here this afternoon.	6	Q. Dr. Frank, are all of your conclusions
·	7	in Exhibit 261?
7 A. Okay.	8	
8 MR. DEAN: Harvey.	i	
9 BY MR. DEAN:	9	Q. And all of your observations about this
10 Q. Okay. What do you conceive your role to	10	case would be included in either Exhibit 50 and
11 be as an expert witness in this case?	11	Exhibit 261; correct?
12 A. I was asked to comment on two things:	12	A. Yes.
13 The adequacy of the pharmacovigilance processes and	13	Q. Thank you.
14 the impact on any signal detection in regard to the	14	A. Now, please yes or no? Okay.
15 Digitek case.	15	MR. THOMPSON: Just let Dick ask you a
16 It was I was asked only on the	16	question.
17 systems. I was not provided any information on the	17	BY MR. DEAN:
18 content, the MedWatch, the PSURs, that would allow		Q. So we can agree that you did not look at
19 to actually do the signal detection or the trending.	19	the underlying any underlying AER reports on
20 The scope of my work was limited.	20	Digitek; correct?
2 1 I was also asked to comment on changes	21	A. I did not receive any MedWatch forms or
22 in the risk communication that occurred between the	22	CIOMS forms. I did not receive any PSURs, any U.S.
23 Health Hazard Assessment of Dr. Leikin, the letter to	23	Periodic Reports, or any other aggregate reports to
24 the Dear Customer, the business-to-business letter to	24	any health authority.
25 Mylan and UDL, and then the public press release.	25	MR. KAPLAN: I can't hear you.
Page 7	1	Page 73
1 I could not find any evidence of Dear	1	THE WITNESS: I did not receive any
2 Doctor or Dear Patient letters.	2	MedWatch forms, any CIOMS forms, any PSURs, ICH PSURs,
3 So when I was asked to look at the	3	no U.S. Periodic Reports, or any other form of
4 changes in those communications, I documented that	4	aggregate reporting to the health authorities.
5 absence and said, I am going from Health Hazard	5	The only information that I received was
6 Assessment to a business-to-business Dear Customer	6	Dr. Leikin's final health assessment, Health Hazard
7 letter, and then the communication to the health care	7	Assessment, and FDA FDA inspection 483s,
8 community and the patients is restricted to the press	8	Establishment Inspection Reports, and the resultant
9 release.	9	letters between the FDA and Actavis or Amide.
10 There is not additional communication in	10	BY MR. DEAN:
the form of Dear Doctor and Dear Patient letters. My	11	Q. And I don't want to harp on this, but I
12 comments are restricted to those two spheres and then	12	asked this is for furtherance of our proceedings
13 merged into one document with the supporting evidence	1	today, I simply asked whether you had received the
14 Q. Does Exhibit 261 contain all of your	14	MedWatch, the AERs and the MedWatch reports.
15 opinions in this case?	15	You told me no. And then you went on
16 A. This is the conclusion. There are	16	and gave me a whole other list of things.
17 comments in the supporting document that are also	17	I would simply ask that, as we go along
18 expressions of opinions. It is possible that all of	18	today, you listen to my question and answer my
the comments in the supporting document have not bee		question. Is that agreeable?
20 completely abstracted to the conclusion.	20	A. Yes.
	21	Q. Okay. Thank you.
Because my original intent was to	22	And so since you did not have the
22 provide this document with this conclusion following	23	MedWatch forms in regard to Digitek, you would have
23 this, so that you would go through this seeing the	ı	<del>-</del>
24 timeline that also notes some of the changes of	2/	necessarily been unable to engage in any signal
timeline that also notes some of the absences of information, and then the information that I read and	24 25	necessarily been unable to engage in any signal detection analysis; correct?

Videotaped

	Page 74		Page 76
,		1	submitted to the FDA, they list events.
1	MR. THOMPSON: Object to the form.	2	The assumption is that when the FDA is
2	BY MR. DEAN: Q. Go ahead, Doctor. You can answer the	3	talking about adverse events, whether they be 15-day
3	- '	4	reports that are not submitted or adverse events that
4	question.	5	where they did not like the adequate the
5	A. I'm going to say yes, it precludes		adequacy of the narrative quality or the follow-up,
6	definitive assessment. The reason I went on too long	6 7	when they list the event, the date, the drug, and the
7	with your original question is to list all of the		I'm sorry the case number, the date and the drug
8	documents that I could recall that contain any	8	,
9	information abstracted from the MedWatches.	9	and then the events that follow, the assumption is that that is the coding that was done on the
10	What I received, and I did discuss this	10	narrative, the events associated with the MedWatch.
11	with them last night, was abstracted information that	11	They do comment that there were problems
12	was usually the coding, the ADR coding, that really	12	
13	precluded definitive assessment of any single case and	13	with the events being left out of the appropriate box
14	really any aggregate analysis.	14	of the MedWatch.
15	Q. So you didn't have the information to do	15	Q. Is what you have described, does it
16	that, did you?	16	contain actual coding or does it contain or is it
17	A. No. The only thing I had provided to me	17	are they documents from which you've assumed a
18	was Dr. Leikin's Health Hazard Assessment where I	18	coding?
19	could use the information that he provided in that to	19	A. It is an assumption on my part. I
20	assess his conclusions.	20	have
21	But I felt that report did not contain	21	Q. So so the only let's get back to
22	enough detail to allow me to make a full, independent	22	my original question.
23	assessment, in that he included only a table of the	23	The only coding on MedWatches that you
24	events and I was not given as an appendix to that the	24	have seen is what is contained in the Health Hazard
25	company internal signal detection report that he was	25	Evaluation form; is that correct?
		1	
E	Page 75		Page 77
1	Page 75 provided.	1	Page 77 A. And I am
1 2		1 2	A. And I am Q. Is that correct?
1	provided.	l	A. And I am
2	provided.  Q. You said a minute ago that you had seen	2	<ul> <li>A. And I am</li> <li>Q. Is that correct?</li> <li>A. I have to clarify the yes or no because</li> <li>you</li> </ul>
2 3	provided.  Q. You said a minute ago that you had seen some coding on the MedWatch reports.	2 3	<ul><li>A. And I am</li><li>Q. Is that correct?</li><li>A. I have to clarify the yes or no because</li></ul>
2 3 4	provided.  Q. You said a minute ago that you had seen some coding on the MedWatch reports.  What coding did you see and in what document did you see it?  A. The coding would be in the table of	2 3 4	A. And I am Q. Is that correct? A. I have to clarify the yes or no because you Q. Well, could you answer first before you clarify?
2 3 4 5	provided.  Q. You said a minute ago that you had seen some coding on the MedWatch reports.  What coding did you see and in what document did you see it?	2 3 4 5	A. And I am Q. Is that correct? A. I have to clarify the yes or no because you Q. Well, could you answer first before you clarify? This is very simple. Have you seen any
2 3 4 5 6	provided.  Q. You said a minute ago that you had seen some coding on the MedWatch reports.  What coding did you see and in what document did you see it?  A. The coding would be in the table of	2 3 4 5 6	<ul> <li>A. And I am</li> <li>Q. Is that correct?</li> <li>A. I have to clarify the yes or no because you</li> <li>Q. Well, could you answer first before you clarify?</li> <li>This is very simple. Have you seen any coding on a MedWatch report on Digitek other than what</li> </ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 .18 19 20 21 22 23	provided.  Q. You said a minute ago that you had seen some coding on the MedWatch reports.  What coding did you see and in what document did you see it?  A. The coding would be in the table of Dr. Leikin's Health Hazard Assessments where he has the events. My assumption is that the events listed were events coded.  I do not know that he did not go to the narrative and take out events that were not coded. I am making an assumption. There are similar abstractions in the  Q. Excuse me. Let me just stop you.  So the only coding I want to focus on my question.  The only coding was what is in the Health Hazard Evaluation form that Dr. Leikin did; whatever codes appear there are the only codes you've seen on MedWatch reports; is that correct?  A. No.  Q. Okay. What else have you seen?  A. The FDA inspectors, when they go back	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. And I am Q. Is that correct? A. I have to clarify the yes or no because you Q. Well, could you answer first before you clarify? This is very simple. Have you seen any coding on a MedWatch report on Digitek other than what may be contained in that Health Hazard Evaluation form? A. I have not seen any MedWatch forms with coding. I made the assumption that Dr. Leikin constructed the table in the Health Hazard Assessments from the coding on the cases. But I was not able to verify that table against the coding on the MedWatch forms. MR. DEAN: Excuse me. There's one with just the Health Hazard Evaluation, the document. BY MR. DEAN: Q. Dr. Frank, I have I hand you VIDEO OPERATOR: Your microphone. BY MR. DEAN: Q. I hand you what we've marked as Exhibit

-	Page 78		Page 80
1	A. Yes.	1	A. Yes.
2	Q. And the you've been talking about	2	Q. Well, I a few minutes ago I asked you
3	coding. Are you referring to the chart?	3	about the scope, your understanding about what your
4	A. When you look at the table here well,	4	assignment was, and you told me the two topics that
5	actually, what I'm really referring to is the table.	5	you were asked to address.
6	The column that says, Adverse Events,	6	What do you understand your role to be
7	and they list these, my assumption is that these	7	in this case as far as how you present the
8	events will map to the adverse events on the CIOMS or	8	information?
9	the MedWatch forms and the coding in the database.	- 9	Do you view yourself as an advocate on
10	Q. And so that's what you meant before by	10	behalf of the plaintiffs or do you view yourself as an
11	seeing information about coding, you are referencing	11	impartial truth seeker?
12	to this table in Exhibit 220; correct?	12	MR. THOMPSON: Object to the form.
13	A. That, and the FDA inspector's similar	13	BY MR. DEAN:
14	abstractions of events that most likely will map to	14	Q. Go ahead.
15	coding on the MedWatch forms and coding in the adverse	15	A. I have particular concern, because this
16	event databases.	16	is the first time I've been an expert witness, that my
17	Q. Okay. Let's go on.	17	opinions are based on very, very accurate and very,
18	How much are you being paid for your	18	very complete evidence.
19	services in this matter?	19	I became very, very uncomfortable with
20	A. \$150 an hour.	20	the lack of detail in the evidence and the absence of
21	Q. How much time have you spent on this	21	information to that I was provided to completely
22	matter?	22	evaluate the systems in the company.
23	A. Initially, I worked to like the first	23	And what I decided to do to make this
24	week I worked about 35 hours and then I spoke to Smart	24	initial assessment as accurate as possible was to
25	Consulting about how much time they were expecting.	25	track very, very closely with FDA inspectors'
	Page 79	_	Page 81
1	And they said there was no cap.	1	observations that were made by looking at primary
2	And I said, well, the convention on	2	documents that I was not provided.
3	is either a 40-hour cap, a 50-hour cap or a 60-hour	3	And what I have been hired by the
4	cap. And they instructed me to work to a 60-hour cap.	4	plaintiffs, I want to make sure that my opinions are
5	At the end, I was provided these	5	as accurate as possible.
6	additional the additional documents in a short time	6	It's been a little bit embarrassing when
7	frame, and I worked extra hours.	7	you asked me questions and you see that I'm doing
8	And then I talked to Smart Consulting	8	sketching notes to myself. I don't write out official
9	about whether I should bill over the cap, and they	9	lists and hand them to the attorneys.
10	instructed me to bill it.	10	I want as little, I want to say,
11	Q. So as you	11	embarrassment as possible, that will result from my
12	MR. KAPLAN: Instructed you to what? I	12	handling what I see as somewhat of a difficult case.
13	can't hear you. I'm sorry.	13	And this being the first time that I've
14	THE WITNESS: I billed over the 60-hour	14	done this, I don't have experience in having done this
15	cap.	15	before. And I have concerns about the incompleteness
16	MR. KAPLAN: How many?	16	of the information.
17	BY MR. DEAN:	17	There's a fair amount of additional
18	Q. So, as you sit here today, how much time	18	information, such as MHRA inspections, which are very
19	have you billed to this matter?	19	vigorous inspections on compliance, maybe more
20	A. I did not do an aggregate analysis of	20	vigorous than FDA, and there's at least one of them.
21	the time. It is included on this, all of the time	21	But I think that I made a comment that
22	sheets.	22	there were more MHRA inspections.
23	Q. So when we take one of these with us	23	So there's I start to catalog
24	today, when Mr. Thompson and I each take one, we'll	24	inspection one, inspection two, inspection three,
25	have that information; is that correct?	25	through the timeline, identify them as MHRA or FDA,

Videotaped

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Page 84
                                                  Page 82
                                                                               And I started to function more like a
 1
      identify the site, try to specify whether they were
                                                                  1
                                                                       truth seeker. And I don't know how to completely
 2
      actually looking at the pharmacovigilance systems and
                                                                  2
 3
      then map out -- since I don't know what happened from
                                                                  3
                                                                       explain.
                                                                  4
                                                                               I'm extremely concerned that the
 4
      the time the first consent decree was lifted to the
                                                                  5
                                                                       information gathered in the assessment is accurate and
 5
      first inspections to really put down the facts and
                                                                  6
                                                                       complete and can reflect on the signal detection.
 6
      start to build a picture of what happened, what
                                                                  7
                                                                               And I spoke with them last night, and I
 7
      failed, what was corrected, what was adequately
                                                                  8
                                                                       will need to talk to Dr. Miller if you need me to give
 8
      corrected, what was inadequately corrected, and what
                                                                  9
 9
      was found on the repeat FDA inspection of 2008.
                                                                       you further detail on my concerns.
                                                                10
                                                                                But as you sit here, in spite of the
10
               The more that I can get an accurate
                                                                11
                                                                       questions --
      assessment the course of events, it will allow an
11
                                                                               MR. KAPLAN: Mr. Miller? Did you say
                                                                12
12
      accurate assessment of what happened inside the
                                                                13
                                                                       Dr. Miller?
13
      company and any potential impact on signal detection
14
      for either Digitek or any of the other products that
                                                                14
                                                                               THE WITNESS: It's mister.
                                                                15
                                                                               MR. KAPLAN: Pete Miller; correct?
15
      were dependent on those business processes during that
                                                                16
                                                                               THE WITNESS: No, I'm sorry.
16
      period.
                                                                17
                                                                       Mr. Thompson. Mr. Thompson.
                But you've already told us that there's
17
      a substantial amount of underlying company documents
                                                                18
                                                                       BY MR. DEAN:
18
      you have not looked at; correct? Correct?
                                                                                So as of today, you have made your
                                                                19
19
                                                                       concerns about lack of information known to the
20
               I have -- I'm going to have to say a
                                                                20
21
                                                                21
                                                                       plaintiffs' counsel and you've done that in the past.
      simple yes.
                                                                22
                                                                       I understand that, too.
22
          Q.
                Right. And then I wanted to get back to
                                                                23
                                                                                But you did it again last night;
23
       my original question.
                                                                24
                                                                       correct?
24
               And I thank you for your answer.
                                                                 25
               But my original question was how you
25
                                                                          A.
                                                                                Yes.
                                                                                                                  Page 85
                                                  Page 83
                                                                                And you have those concerns, as you sit
                                                                  1
 1
       viewed your role as an expert witness, whether you
                                                                  2
                                                                       here today, that you don't have a full and complete
 2
       viewed yourself as an advocate on behalf of the
                                                                  3
                                                                       information base on which to give your opinion; is
 3
       plaintiffs or whether you viewed yourself as an
                                                                  4
                                                                       that correct?
 4
       impartial observer relating comments about documents
                                                                  5
                                                                                I am privy to some of the information
 5
       that you had reviewed.
                                                                       that was obtained in due diligence on drug
                                                                  6
               Which is -- which role do you see
 6
                                                                  7
                                                                       withdrawals. I'm talking market withdrawals, not
 7
       yourself in, Dr. Frank?
                                                                  8
                                                                       recall of the lots.
 8
               MR. THOMPSON: Object to the form.
                                                                  9
                                                                               And the information obtained in the
 9
       BY MR. DEAN:
                                                                 10
                                                                       discovery of this case was not as extensive in those
10
          Q.
                Go ahead.
                                                                       cases. And I started to ask about the discovery.
                How do I respond to his objection?
                                                                 11
11
          A.
                He's made that for the record. You can
                                                                 12
                                                                               Is this the discovery you would expect
12
          O.
                                                                 13
                                                                       to see in a case like this or are the absence of the
13
       go ahead and give your answer.
                                                                       MHRA inspections? The absence of the company internal
                                                                 14
                Okay. I was hired by the plaintiffs to
14
                                                                       signal document, are those issues?
                                                                 15
15
       address very specific issues, to look how these
                                                                               But there apparently was not a further
       systems potentially impacted signal detection during
                                                                 16
16
                                                                 17
                                                                       investigation done, and I was told not to start to
17
       Digitek recall.
               I needed to do -- I'm going to use a
                                                                 18
                                                                       talk into that direction.
18
                                                                 19
                                                                                As recently as last night, Dr. Frank,
       legal term -- due diligence in the scope of work that
19
                                                                       you expressed an opinion to the plaintiffs' counsel
                                                                 20
20
       they asked me to meet.
                                                                        that you had inadequate information and concerns about
                                                                 21
               In doing that, I became concerned about
21
                                                                        the adequacy of the information to testify today; is
                                                                 22
22
       the completeness of the information that I was seeing
                                                                        that correct?
       and the fact that my opinion based on that information
                                                                 23
23
                                                                 24
24
       could be vulnerable if this information that I don't
                                                                          A.
                                                                 25
                                                                                Okay. Now, you talked about the
25
       have was brought forward.
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Videotaped

	Page 86		Page 88
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	dequacy of signal detection. I want to, in the	1	Q. Okay. And is there a qualifier? Is
	context of Digitek and you understand that product	2	that, indeed, what you're looking for, what you would
	was recalled; correct?	3	be looking for in terms of a manufacturing defect
4	A. Yes.	4	case?
5	Q. In the context of Digitek, would let	5	A. With product complaint cases, I was
	ne strike that.	6	explaining to you that there are often routine Health
7	Your one of your expertises is	7	Hazard Assessments where the pharmacovigilance
-	pharmacovigilance; correct?	8	physician receives work products from quality for the
9	A. Yes. I've worked in the field for	9	product complaint and the investigation and the
	everal years.	10	analytics.
11	Q. Correct.	11	And then there are Health Hazard
12	And, typically, in the field of	12	Assessments done in realtime where the company
	pharmacovigilance, representatives of pharmaceutical	13	pharmacovigilance database is data mined for any cases
	companies are looking at a vast array of information	14	that could indicate that that manufacturing detect was
	o see if new and different adverse reactions are	15	leading to adverse events that were reported, either
	arising from their drugs.	16	globally or particularly in the market of
17	Is that a fair summary?	17	distribution.
18	A. Yes.	18	Some companies will look at the medical
19	Q. And in this case, you this case being	19	literature, and some companies will go as far as to
	he Digitek case, you understand that there is a	20	data mine the AERS database in Washington, which has
	question about a manufacturing defect in the product?	21	which contains all the MedWatch forms submitted to
22	You understand that, don't you?	22	the FDA, or the WHO database in Uppsala, Sweden, that
23	A. Yes.	23	contains all of the CIOMS forms submitted to EMEA.
24	Q. And that is would you agree with me	24	But there is typically, for these
25 t	hat's it's unusual to address a manufacturing	25	manufacturing defects that may have gone to market, an
	Page 87		Page 89
1 d	lefect through signal detection?	1	assessment of the extent of the exposure, what batches
2	I'm not saying it can't be done, but I'm	2	could have been affected, what is the market
3 s	aying it's not the usual thing you do in	3	distribution of those batches, and then is there any
4 p	pharmacovigilance; is that correct?	4	evidence that there are adverse events that are
5	A. Classically, signal detection is looking	5	resulting in response to the market exposure of those.
6 f	or new events.	6	Q. So one of the key things that you want
7	Q. All right.	7	to do is to look at the Adverse Event Reports to see
8	A. But this clustering of cases where the	8	if they suggest a defect in manufacture in affected
	FDA was concerned that they didn't see all of them,	9	batches; correct?
	ny clustering of single cases should alert them to a	10	A. Yes.
11 p	potential batch issue.	11	Q. And the other thing you mentioned in
12	It could be an issue with a site, but it	12	your prior answer was product complaints.
13 a	lso could be could map to an issue with a	13	And so is it also fair to say that if
	listributed batch.	14	one if a company was concerned about a
15	And that should have be covered by an	15	manufacturing defect, they could look to their product
	SOP in the company that will require either a case	16	complaints on returned product and see and make an
17 s	eries or some form of analysis for that cluster of	17	inquiry to see whether those resulted in any adverse
	vents.	18	experience reports?
1.0	Q. So what you are looking for, what you	19	Is that something that companies do?
19	vould be looking for here in terms of signal detection	20	A. You are correct. The work products fed
20 v			to the control of the
20 w	n a manufacturing defect case, is whether whether	21	to pharmacovigilance usually contain an assessment of
20 w 21 ii 22 tl	he MedWatch reports were providing information to the	22	are there any similar product complaint reports. And
20 w 21 ii 22 tl 23 c	he MedWatch reports were providing information to the company that there might be a manufacturing defect;	22 23	are there any similar product complaint reports. And that in turn determines the scope of the batches that
20 w 21 ii 22 tl 23 c	he MedWatch reports were providing information to the	22	are there any similar product complaint reports. And

Videotaped

June 30, 2010

Page 92 Page 90 you want to answer, but you didn't -- you did not --1 1 to move this along. 2 you could not form any opinion as to whether there was 2 What you are looking for -- strike that. 3 What many companies have is a process by 3 communication between the product complaint side and the signal detection side on Digitek as relates to a 4 which there's communication between the folks on the 4 5 signal detection side and folks on the product 5 manufacturing defect because you were not provided 6 with those records, were you? 6 complaint side where they exchange information to see 7 My opinion is not based on the records. 7 if it can be useful to the other side; is that When I inquired on the June 2nd meeting and expressed 8 correct? 8 9 A. 9 my concerns, I was not given enough to document that Yes. 10 10 Q. Is that -- now, did you review the process. 11 deposition of Sarita Thapar? 11 But I found in the FDA inspections of 12 2008 specific statements they were upset about the 12 A. 13 lack of Health Hazard Assessments. 13 Q. Didn't she, indeed, say that Actavis had 14 So what I did in trying to assess 14 such a communication process? 15 15 whether there was an adequacy, realtime Health Hazard A. Yes. 16 Assessments, because I was not -- I was not provided 16 Q. You have not reviewed the product 17 complaints on Digitek prior to the recall, have you? 17 all of the information that you talked about, even on 18 questioning. 18 A. 19 I said, the only thing that I can find 19 You have not reviewed the MedWatch that says that there is perhaps something in place, 20 20 reports prior to the recall, have you? 21 but not in use, was the FDA observation. 21 A. 22 And that's documented in here with my 22 Q. So you don't know whether there were any 23 MedWatch reports which even gave off a signal of a 23 comment about concern of lack of ongoing Health Hazard 24 Assessments. 24 manufacturing defect, do you? 25 And that's the opinion of one 25 A. I went --Page 93 Page 91 investigator; correct? 1 O. Would you answer that question, please. 1 2 The answer is no. 2 A. And I --A. 3 And you don't know whether there were 3 Is that correct? 4 MR. THOMPSON: Object to the form. 4 any product complaints prior to the recall that 5 suggested there was a manufacturing defect, do you? 5 BY MR. DEAN: 6 I do know about the one from 2004 that 6 What you just referenced is the opinion Q. 7 7 of one investigator; correct? led to an investigation. I did not receive the Health 8 Possibly two, but, yes, one. It's one 8 Hazard Assessment in association with that 2004 A. 9 inspection, probably one investigator, possibly two. 9 investigation. 10 Beyond that 2004 incident, which you've 10 Let me go back. Let me go back. And I 11 want to get an answer to my other question, just so 11 talked -- which you just mentioned, have you reviewed 12 any product complaints about Digitek prior to the 12 we're clear. 13 recall? 13 You do not have an opinion as to the 14 14 A. No. I believe all the ones I saw were actual -- strike that. You have not had an opportunity to 15 15 post. review the information exchanged between -- gathered 16 16 Q. So -- right. 17 by the product complaint section and the signal 17 So you don't know whether there was --18 detection section as to -- as to the possibility of 18 at the end of the day, you don't know whether there 19 manufacturing -- strike that. 19 was anything as to Digitek and the manufacturing You have not reviewed the information 20 defect with Digitek to be communicated between the 20 21 obtained by the product complaint section and the 21 product complaint section and the signal detection 22 signal detection section prior to the time of the 22 section, do you? I went looking to assess what was done, 23 recall to determine the adequacy of the information 23 A. and I couldn't find anything. And then --24 exchanged between the two groups, have you? 24 Could you -- I'll let you answer however 25 I have concern that there is an absence 25

24 (Pages 90 to 93)

	Page 94		Page 96
1	of information provided to me at this point in time on	1	to class black box labelings, and they put together a
2	which I can base an opinion.	2	labeling review and sent it in to the FDA, and I was
3	Q. You haven't reviewed that information at	3	assigned it and I started on it.
4	this point, have you?	4	Q. Let me interrupt and see if I can speed
5	A. No.	5	this along.
6	Q. Correct? Is that correct?	6	Would it be fair to say that when you
7	A. The information that I	7	were at the FDA, you basically did medical review of
8	MR. KAPLAN: Is that correct?	. 8	INDs, NDAs, and addressed labeling issues?
9	THE WITNESS: No, I have not been	9	Is that a fair summary?
10	provided that information.	10	MR. THOMPSON: Object to the form.
11	BY MR. DEAN:	11	THE WITNESS: I did. I also did some
12	Q. Thank you.	12	review of
13	Could you tell us, and I don't want to	13	BY MR. DEAN:
14	I hope we don't spend much time on this, but I	14	Q. Just give me the other broad areas that
15	would just like for you to give us a brief overview of	15	you might I don't need the detail, but just a broad
16	your job duties at the FDA, what you did when you were	16	area.
17	at the FDA.	17	A. I did some peer review of or I did
18	Could you do that for us, please?	18	some review of peer-reviewed literature that came into
19	A. I spent two years at the FDA as a fellow	19	the FDA for FDA review prior to publication, because
20	in the division of cardio-renal drug products.	20	there had been disputes between peer-reviewed
21	And when I finished my fellowship, I was	21	publications and the FDA in that the peer-reviewed
22	brought on as a GS-14 expert level reviewer in anti-	22	publications were talking too much about off-label
23	infectives for the small molecules for sepsis and	23	use.
24	septic shock that had been moved from cardio-renal to	24	Q. Okay. Go ahead. Anything else?
25	anti-infectives.	25	A. I assisted on the placebo hypertension
	Page 95		Page 97
1	_	1	•
1 2	They needed cardiovascular expertise.	1 2	project where they pooled placebo data on hypertension
2 .	They needed cardiovascular expertise.  I also reviewed things in anti-infective	2	project where they pooled placebo data on hypertension trials to justify the use of placebo groups in short-
3	They needed cardiovascular expertise.  I also reviewed things in anti-infective products. I	2 3	project where they pooled placebo data on hypertension trials to justify the use of placebo groups in short-term Phase II trials demonstrating pharmacodynamic
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	Page 98		Page 100
1		1	A. Yes.
1	Q. When you were in	2	Q. Okay. So you do have some knowledge on
2	A. There was I was made aware of that, but I was not involved with it. I take that back.	3	that, don't you?
3.		4	A. Yes.
4	Q. I know that you have a work history in	5	Q. And you would agree with me that the 483
5	private industry as well.	6	form itself says it's not a final agency action;
6	During your time in private industry,	7	correct?
7	did have any experience with pharmaceutical recalls?	8	A. Yes.
8	A. I did not implement the recalls. I did the Health Hazard Assessments for them.	9	Q. I take it, you're not going from your
9		10	report, you're not going to testify about issues of
10	Q. So that would the extent of your involvement with a recall would be to do the Health	11	adulteration; is that correct?
11		12	A. No. They've asked me to be very
12	Hazard Evaluation; correct?	13	specific in testifying on issues of these systems and
13	A. Yes.	14	not to go out of scope into issues that would be
14	Q. Okay. Isn't it true that the FDA can	15	covered by the cardiologists.
15	ask that a product be recalled for any reason?	16	Q. Well, just so I'm clear, you're not
16	A. I will say yes.	17	going to say that because a drug is adulterated, it's
17	Q. Okay. And there is no legal requirement	18	defective? You're not going to offer an opinion like
18	that a product be defective before it's subject to a	19	that, are you?
19 20	recall, is there?  A. I do not know the answer to that	20	A. No.
	question. I cannot think of that where that is	21	Q. Okay. And you're not going to be
21	stipulated in the CFR.	22	offering any medical opinions on individual cases;
23	Q. Has any company that you've ever worked	23	correct?
24	for received a 483?	24	A. No.
25	A. Yes.	25	Q. I'm correct, you're not?
		<u> </u>	
1	Dago 00	I	Page 101
	Page 99	_	Page 101
1	Q. Has any company you've ever worked for	1	A. Correct. I am not.
2	Q. Has any company you've ever worked for received a warning letter?	2	<ul><li>A. Correct. I am not.</li><li>Q. Okay. Thank you.</li></ul>
2 3	<ul><li>Q. Has any company you've ever worked for received a warning letter?</li><li>A. Yes.</li></ul>	2 3	<ul><li>A. Correct. I am not.</li><li>Q. Okay. Thank you.</li><li>Would you agree that if the FDA, in its</li></ul>
2 3 4	Q. Has any company you've ever worked for received a warning letter?  A. Yes.  May I ask a clarifying question?	2 3 4	<ul> <li>A. Correct. I am not.</li> <li>Q. Okay. Thank you.</li> <li>Would you agree that if the FDA, in its dealings with a company, has concerns about data</li> </ul>
2 3 4 5	<ul> <li>Q. Has any company you've ever worked for received a warning letter?</li> <li>A. Yes.</li> <li>May I ask a clarifying question?</li> <li>Q. No.</li> </ul>	2 3 4 5	A. Correct. I am not. Q. Okay. Thank you. Would you agree that if the FDA, in its dealings with a company, has concerns about data integrity, it will take aggressive action vis-a-vis
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Has any company you've ever worked for received a warning letter?  A. Yes.  May I ask a clarifying question?  Q. No.  A. Okay.  Q. What is a 483?  A. A 483 is an FDA form in which the inspectors report their initial observations of the inspection.  Q. Is it a final agency action?  A. It is taken back into the FDA and it produces a warning letter.  Q. Is it a final agency action?  A. I do not know the answer to that question. In legal terms, if it's if it what constitutes a final agency action. I never  Q. Did you review any of the 483s in this case?  A. Yes.  Q. Did you do you have any recollection of observing on the 483s whether it speaks to that issue that I just asked you about?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Correct. I am not. Q. Okay. Thank you. Would you agree that if the FDA, in its dealings with a company, has concerns about data integrity, it will take aggressive action vis-a-vis that company? MR. THOMPSON: Object to the form. THE WITNESS: Please repeat the question. BY MR. DEAN: Q. In your experience, if the FDA has questions about data integrity within a company, will it take aggressive actions to follow up with that company? A. Yes. Q. In your review of the documents you've been provided, you didn't see any indication that the FDA had any such concerns; correct? A. There were no explicit statements on data integrity. There were, however, inspection observations of inaccuracies and incompleteness of narratives and coding on MedWatch forms. Incomplete coding on MedWatch forms can
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Videotaped

	Page 102		Page 104
1	I have not seen any coding conventions	1	Q. Is the only information that you would
2	from Actavis, and I have not seen any primary	2	have in response to my question what would be
3	documents that would allow me to make any further	3	contained in an FDA document? Is that fair?
4	statement of the impact of coding issues on signal	4	A. Unless there is something in I was
5	detection.	5	sent sample product complaints toward the end, and I
6	But the FDA inspector's observation	6	did not loop them in as evidence. They are on the
7	raised concerns about quality issues in the safety	7	flash drive.
8	database, coding and the case retrieval for signal	8	I cannot recall any specifics right now
9	detection. I can't comment on the extent.	9	of those. But there may be on those product
10	Q. Would you agree that in the context of	10	complaints statements that I do not recall about
11	the AERs that you're testing testifying about, the	11	double-thick tablets. I cannot recall them.
12	FDA never raised a specific question in regard to data	12	So I have to say no. The only thing
13	integrity?	13	that I am absolutely certain that I have seen is 2004.
14	Do you agree with that?	14	Q. Okay. And let me ask you a few follow-
15	A. That term was not in any of the	15	up questions in regard to that.
16	documents that I reviewed.	16	MR. DEAN: Why don't we go off the
17	Q. Do you have any knowledge as to whether	17	record for just a minute while I find this document.
18	a double-thick tablet of Digitek ever reached the	18	VIDEO OPERATOR: Going off the video
19	market?	19	record.
20	Do you have any specific knowledge of	20	The time is 11:38 a.m.
21	that?	21	(Discussion off the record.)
22	A. The only evidence I have that a double-	22	VIDEO OPERATOR: We're now back on the
23	thick tablet reached the market is the 2004 inspection	23	video record.
24	report where a double-thick tablet was returned to the	24	The time is 11:40 a.m.
25	company from a pharmacist in Bellingham, Washington.	25	BY MR. DEAN:
	oompany nom a practical and a second	ļ	
	Page 103		Page 105
1	Page 103	1	Page 105
1 2	I cannot recall from the product	1 2	Q. In your report, which we marked, you
2	I cannot recall from the product complaints that I reviewed if there's specific	2	Q. In your report, which we marked, you reference that 2004
2 3	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and	2	Q. In your report, which we marked, you reference that 2004 A. Yes.
2 3 4	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.	2 3 4	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you
2 3 4 5	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms,	2 3 4 5	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA.
2 3 4 5 6	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall	2 3 4 5 6	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA. Did you inquire as to the plaintiffs'
2 3 4 5 6 7	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall product that was incinerated, that would allow me to	2 3 4 5 6 7	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA. Did you inquire as to the plaintiffs' lawyers whether the FDA itself did any follow-up on
2 3 4 5 6 7 8	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall product that was incinerated, that would allow me to make any assessment of how many or the percentage of	2 3 4 5 6	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA. Did you inquire as to the plaintiffs' lawyers whether the FDA itself did any follow-up on the 2004 double thick observation?
2 3 4 5 6 7 8	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall product that was incinerated, that would allow me to make any assessment of how many or the percentage of any batch of double-thick tablets that reached the	2 3 4 5 6 7 8	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA. Did you inquire as to the plaintiffs' lawyers whether the FDA itself did any follow-up on the 2004 double thick observation? A. No.
2 3 4 5 6 7 8 9	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall product that was incinerated, that would allow me to make any assessment of how many or the percentage of any batch of double-thick tablets that reached the markets.	2 3 4 5 6 7 8 9	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA. Did you inquire as to the plaintiffs' lawyers whether the FDA itself did any follow-up on the 2004 double thick observation? A. No. Q. Do you know whether the company reported
2 3 4 5 6 7 8 9 10	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall product that was incinerated, that would allow me to make any assessment of how many or the percentage of any batch of double-thick tablets that reached the markets.  Q. Is the only one that you are aware of	2 3 4 5 6 7 8 9 10	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA. Did you inquire as to the plaintiffs' lawyers whether the FDA itself did any follow-up on the 2004 double thick observation? A. No. Q. Do you know whether the company reported it to the FDA?
2 3 4 5 6 7 8 9 10 11	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall product that was incinerated, that would allow me to make any assessment of how many or the percentage of any batch of double-thick tablets that reached the markets.  Q. Is the only one that you are aware of the one you referenced in 2004?	2 3 4 5 6 7 8 9 10 11	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA. Did you inquire as to the plaintiffs' lawyers whether the FDA itself did any follow-up on the 2004 double thick observation? A. No. Q. Do you know whether the company reported it to the FDA? A. No.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I cannot recall from the product complaints that I reviewed if there's specific evidence in those. I would have to re-review them and report back to you.  But I have no MedWatches, CIOMS forms, or aggregate reports, or any information on the recall product that was incinerated, that would allow me to make any assessment of how many or the percentage of any batch of double-thick tablets that reached the markets.  Q. Is the only one that you are aware of the one you referenced in 2004?  A. There has been reference to a 2008, but I cannot recall that I was provided any documents on that case in 2008.  Q. Do you know whether what's your understanding as to double-thick tablets in 2008, if you have any?  A. Something was mentioned this morning. But what I have are the inspection reports and the recall package to finding the batches at risk.  I cannot picture in any documents sent	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. In your report, which we marked, you reference that 2004 A. Yes. Q double thick observation. But you did not reference any follow-up by the FDA. Did you inquire as to the plaintiffs' lawyers whether the FDA itself did any follow-up on the 2004 double thick observation? A. No. Q. Do you know whether the company reported it to the FDA? A. No. Q. Would you have expected the company to report it to the FDA? A. I'm going to say yes, it should have generated a field alert. But I must qualify that, that it's not my area of expertise. Q. Would this would the FDA follow would the possibility of an FDA follow-up to this 2004 observation be within one of the white spaces you mentioned before? A. Yes.

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	Page 106		Page 108
1	recognize what kind of a document this is?	1	A. Yes.
2	A. This is an inspection. It's a CGMP	2	Q. And then it says, corrective actions
3	inspection.	3	were verified during the inspection; correct?
4	Q. And was it prepared by it was	4	A. Yes.
5	prepared by the FDA; correct?	5	Q. And you have no reason to disagree with
6	Look at the back of it.	6	any of the conclusions reached by the FDA in this
7	A. Yes.	7	Field Alert in regard to the 2004 double thick
8	Q. And on the front page, on the bottom	8	observation, do you?
9	under Administrative Procedures, it says, We,	9	A. No.
10	Investigators Erin McCaffrey and Robert Horan, issued	10	Q. Okay. Now, is this the kind of document
11	a 482 Notice of Inspection; correct?	11	that you would have liked to have seen when you were
12	A. Yes.	12	compiling your report, at least a part of it, in
13	Q. So this is the FDA inspectors inspecting	13	regard to the 2004 double thick issue?
14	Actavis in 2004; correct?	14	A. Yes. It would have assisted in this
15	A. Yes.	15	timeline, and of documenting corrective actions and
16	Q. In December of 2004; correct?	16	adequacy of corrective actions over this period.
17	A. 12/1/04, yes.	17	Q. Because that's one thing you're looking
18	Q. Okay. Now, let me direct you your	18	for; right?
19	attention to Page 6 of this report.	19	A. Yes.
20	Do you see where it says, Field Alert	20	Q. And here they did Actavis did exactly
21	Reporting?	21	that, they reported it, they took corrective actions,
22	A. Yes.	22	and the FDA was satisfied with those corrective
23	Q. Before I ask you the next series of	23	actions; correct?
24	questions, could you just take a minute and read that	24	A. Yes. In December of 2001, it is clearly
25	paragraph, please.	25	documented
	paragraph, prease.	122	documented
	D 107		Dawa 100
	Page 107		Page 109
1	A. Yes.	1	Q. I'm sorry, December 2004.
2	A. Yes. (Witness reviews document.) Okay.	2	Q. I'm sorry, December 2004. A. 2004. In December 2004, this document
	<ul><li>A. Yes.</li><li>(Witness reviews document.) Okay.</li><li>Q. So, first of all, we can agree that the</li></ul>	2	Q. I'm sorry, December 2004. A. 2004. In December 2004, this document clearly states that the Field Alert was issued. There
2 3 4	<ul> <li>A. Yes.</li> <li>(Witness reviews document.) Okay.</li> <li>Q. So, first of all, we can agree that the</li> <li> in the first two sentences it says that the a</li> </ul>	2 3 4	Q. I'm sorry, December 2004. A. 2004. In December 2004, this document clearly states that the Field Alert was issued. There was inspection follow-up.
2 3 4 5	A. Yes.  (Witness reviews document.) Okay.  Q. So, first of all, we can agree that the in the first two sentences it says that the a Field Alert was issued and it was submitted to the New	2 3 4 5	Q. I'm sorry, December 2004. A. 2004. In December 2004, this document clearly states that the Field Alert was issued. There was inspection follow-up.  My reading of this paragraph includes
2 3 4	A. Yes. (Witness reviews document.) Okay. Q. So, first of all, we can agree that the in the first two sentences it says that the a Field Alert was issued and it was submitted to the New Jersey District Office; correct?	2 3 4 5 6	Q. I'm sorry, December 2004. A. 2004. In December 2004, this document clearly states that the Field Alert was issued. There was inspection follow-up.  My reading of this paragraph includes that the FDA is actually confirming some of the
2 3 4 5	A. Yes.  (Witness reviews document.) Okay.  Q. So, first of all, we can agree that the in the first two sentences it says that the a Field Alert was issued and it was submitted to the New Jersey District Office; correct?  A. Yes.	2 3 4 5 6	Q. I'm sorry, December 2004. A. 2004. In December 2004, this document clearly states that the Field Alert was issued. There was inspection follow-up.  My reading of this paragraph includes that the FDA is actually confirming some of the conclusions of the report that I received. We can
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. (Witness reviews document.) Okay. Q. So, first of all, we can agree that the in the first two sentences it says that the a Field Alert was issued and it was submitted to the New Jersey District Office; correct? A. Yes. Q. So Actavis submitted this as a Field Alert to the District Office; correct? A. Uh-huh. Q. Yes? A. Yes. Q. And then the FDA, when they were there during this inspection, did follow-up on that; correct? A. Yes. Q. And the FDA noted that, besides this one	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. I'm sorry, December 2004. A. 2004. In December 2004, this document clearly states that the Field Alert was issued. There was inspection follow-up.  My reading of this paragraph includes that the FDA is actually confirming some of the conclusions of the report that I received. We can verify that point by point if we need to.  And they are saying at that time they consider the corrective actions to be verified. And my assumption is verification means adequate.  Q. Okay. Thank you. Let me get that out of your way.  Have you ever taught or published about pharmacovigilance?  A. I gave internal seminars inside CSC.  Q. Inside what?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes.  (Witness reviews document.) Okay.  Q. So, first of all, we can agree that the  in the first two sentences it says that the a  Field Alert was issued and it was submitted to the New  Jersey District Office; correct?  A. Yes.  Q. So Actavis submitted this as a Field  Alert to the District Office; correct?  A. Uh-huh.  Q. Yes?  A. Yes.  Q. And then the FDA, when they were there during this inspection, did follow-up on that; correct?  A. Yes.  Q. And the FDA noted that, besides this one tablet, no additional complaints or reports of thick tablets have been received for this high-volume product; correct?  A. Yes.  Q. And they further concluded the event was considered an isolated incident and corrective actions	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. I'm sorry, December 2004. A. 2004. In December 2004, this document clearly states that the Field Alert was issued. There was inspection follow-up.  My reading of this paragraph includes that the FDA is actually confirming some of the conclusions of the report that I received. We can verify that point by point if we need to.  And they are saying at that time they consider the corrective actions to be verified. And my assumption is verification means adequate.  Q. Okay. Thank you. Let me get that out of your way.  Have you ever taught or published about pharmacovigilance?  A. I gave internal seminars inside CSC.  Q. Inside what?  A. Inside one of the consulting firms that I worked for. The they had approached me about talking at national conventions, but I did not. And, no, I have no publications on pharmacovigilance.  Q. And you've never taught in outside of the context in which you just mentioned; right?

28 (Pages 106 to 109)

Videotaped

	Page 110		Page 112
1	official company SOP training on pharmacovigilance.	1	And if you don't, that's fine.
		2	A. No. It's a working committee within the
2	Q. Now, can we agree that MedWatch reports the information in MedWatch reports that's received	3	WHO that repeatedly analyzes pharmacovigilance
3	does not mean that a drug caused a specific adverse	4	practices and publishes recommendations that are
4	event that may be described in the report?	5	available through the WHO in Geneva, but I'm blanking
5	-	6	on the actual acronym.
6		7	Q. And that's fine. So
7	Q. It doesn't even try to do that, does     it? A MedWatch report does not even attempt to do	8	MR. KAPLAN: I think it's S-C-I-O-M-S.
8	·	9	THE WITNESS: It's C-I-O-M-S.
9	that; correct?	10	MR. KAPLAN: It's S-C.
10	A. The MedWatch form does not, but the CIOMS reports contain CIOMS comments.	11	THE WITNESS: It's C. Charlie, Ingrid,
11 12	So in the database, there can be CIOMS	12	Oliver, Mark, Sam.
13	comments that will map if the database prints to a	13	MR. KAPLAN: See what I know? Not very
14	CIOMS form, and I do not believe they will map to the	14	much.
15	FDA 3500, the MedWatch.	15	BY MR. DEAN:
	But there can be assessments of	16	Q. And is this a group that takes a number
16 17	reporters and company on the MedWatch and the CIOMS,	17	of MedWatches and tries to analyze or synthesize them
18	and CIOMS companies assessing all of that information	18	and issue a report?
19	in light of the narrative on the CIOMS and in the	19	What is it that they do? I wasn't quite
20	database.	20	sure what you were saying that they did.
21	Because one of the very important things	21	A. No. They actually do higher level work
22	in a company when you have the databases, there is a	22	that actually translates into recommended
23	reporter's field for causality or relatedness	23	recommendations for best practices in
24	relatedness, and there's a company field.	24	pharmacovigilance.
25	And you want those two to be in parallel	25	Q. But they don't take an individual
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	Dawa 111	ļ	. Dage 113
	Page 111	_	Page 113
1	and transparent.	1	MedWatch report and try to tease out causality from an
2	and transparent.  Occasionally you hear stories of	2	MedWatch report and try to tease out causality from an individual MedWatch report, do they?
2 3	and transparent.  Occasionally you hear stories of companies who say we only need one field and the	2 3	MedWatch report and try to tease out causality from an individual MedWatch report, do they?  A. No. But the CIOMS form is the XUS
2 3 4	and transparent.  Occasionally you hear stories of companies who say we only need one field and the company can overwrite the reporters.	2 3 4	MedWatch report and try to tease out causality from an individual MedWatch report, do they?  A. No. But the CIOMS form is the XUS equivalent of the FDA 3500.
2 3 4 5	and transparent.  Occasionally you hear stories of companies who say we only need one field and the company can overwrite the reporters.  But it is extremely important to	2 3 4 5	MedWatch report and try to tease out causality from an individual MedWatch report, do they?  A. No. But the CIOMS form is the XUS equivalent of the FDA 3500.  Q. Okay.
2 3 4 5 6	and transparent.  Occasionally you hear stories of companies who say we only need one field and the company can overwrite the reporters.  But it is extremely important to maintain two transparent fields with a reporter	2 3 4 5 6	MedWatch report and try to tease out causality from an individual MedWatch report, do they?  A. No. But the CIOMS form is the XUS equivalent of the FDA 3500.  Q. Okay.  A. And when these databases are
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	and transparent.  Occasionally you hear stories of companies who say we only need one field and the company can overwrite the reporters.  But it is extremely important to maintain two transparent fields with a reporter assessment of relatedness, a company assessment of relatedness.  The company assessment of relatedness may be based on a probabilistic analysis, such as the Naranjo algorithm, and all of that is typically put into a CIOMS comment that also resides in the database.  Q. Let's go back. First of all, a MedWatch report itself does not even attempt to get at the issue of causation; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MedWatch report and try to tease out causality from an individual MedWatch report, do they?  A. No. But the CIOMS form is the XUS equivalent of the FDA 3500.  Q. Okay.  A. And when these databases are constructed, the fields are in the databases and there's there's a menu that allows the company to print out the FDA form, the CIOMS form for the EMEA, the specific form that goes to the BfArM in Germany, on and on and on.  The same fields in the databases are mapping to country-specific forms. They can submit the CIOMS form to the FDA in lieu of the 483.  Q. In lieu of the AER?  A. In lieu of the MedWatch
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#### Page 114 Page 116 1 Q. Have you been informed that a company 1 Yes. Now --A. 2 called UDL did -- I'm sorry. 2 Is that correct? Q. 3 Have you been informed that a company 3 A. 4 And then if it -- so if it contains the 4 called Celsius did testing on Digitek that was on the Q. 5 market prior to the time of the recall? 5 same information, it would not attempt to get at 6 No. However, I did not, nor did I ask 6 causality, either, would it? 7 for this. My assumption is that these documents would 7 A. They do not have a hundred percent 8 have routed to an expert witness who was actually 8 concordance. 9 expert in that area. 9 The CIOMS forms contain CIOMS comments, 10 10 And that's outside your area of which are typically a statement of causality, based on O. expertise, product -- product manufacture and testing; 11 11 the reporter's causality, the medical judgment on the 12 narrative, plus or minus a quantitative probabilistic 12 correct? 13 A. Yes. 13 algorithm on causality, such as the Naranjo. Did either Mr. Miller, Ms. Johnson or 14 But you have a number of reviewers that 14 Q. Mr. Thompson tell you that the plaintiffs' lawyers in 15 15 are looking at a particular report; correct? Yes. And there could be discordance in this litigation had publicly abandoned the theory of 16 16 17 their assessments. And that's why I made the point of 17 double-thick tablets? 18 A. No. 18 the importance of the transparency of the reporter's 19 19 assessment of causality and the company's assessment Q. Would that surprise you to learn about 20 that? 20 of causality. MR. THOMPSON: Object to the form. 21 21 Those are to be considered independent 22 BY MR. DEAN: 22 and recorded in parallel and transparent. And if the 23 23 company wishes to refute the reporter, they can do so, Q. Would it surprise you to know that 24 Mr. Thompson has filed papers with the court that says 24 but they cannot overwrite or obliterate the reporter's 2.5 the whole issue of double-thick tablets is a red 25 causality. Page 117 Page 115 1 Do you have any evidence -- for the herring? 1 2 MR. THOMPSON: Object to the form. purposes of this question, I want to put aside the 2 3 THE WITNESS: I was not informed of 3 double thick issue. that. I -- I was aware that they were going to pursue 4 A. Okay. 4 5 5 the batch uniformity issue, but I was not aware the Do you have any evidence that any normal Q. 6 double-thick tablet issue had been abandoned. 6 size Digitek tablet reached the market which was out 7 7 of specification prior to the time of the recall? BY MR. DEAN: 8 Would you have bothered to put any 8 A. 9 reference to double-thick tablets in your report if 9 Okay. Do you -- are you aware that --Q. 10 you had known that the theory had been abandoned and 10 are you aware of something called an FDA 484? that plaintiffs were referring to it as a red herring? 11 11 Would you clarify? MR. THOMPSON: Object to the form. Are you aware that sometimes the FDA 12 12 13 13 will, unbeknownst to a particular company, go out and THE WITNESS: No. I was asked specifically to evaluate the 14 14 obtain product from the market and test it to see if systems and the impact on the signal detection in the 15 it meets specifications? 15 16 Digitek case, and they were discussing the double-16 I have heard of that procedure. I have A. 17 thick tablet and the blend issue, but I was not told 17 not been formally trained on it, nor have I been formally involved in it. And I was not the recipient 18 the double-thick tablet had been abandoned. 18 19 I was not shown the FDA press release 19 of the reports from that procedure when I was at the 20 stating that there was no risk to public health in the 20 FDA. Digitek recall. And I have no information that allows 21 21 Have you been informed in this case that me to quantify the statistical probability of the 22 the FDA indeed went out and tested Digitek that was on 22 impact of the blend issue. 23 23 the market prior to the time of the recall? 24 These were maintained as abstract risks, 24 A. No. I have not been informed verbally and most of the information that I would have needed 25 25 or in writing.

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## Page 120 Page 118 1 And when you say that, establish a risk to determine any probability was redacted out of what 1 from double thick or a blend issue, you don't mean by 2 2 I received. looking at manufacturing records, you mean by looking 3 3 In other words, how many tablets were at records within your area of expertise; right? 4 4 actually in a batch, what was the likelihood that 5 Well, as an FDA medical reviewer, we 5 those batches -- those tablets all ended up in one 6 have classes on a lot of this. We don't become 6 bottle and ingested by one patient or evenly 7 expert. But I started to ask questions of the risk of 7 distributed throughout a -- throughout bottles, one population exposure. Is this one tablet per batch or tablet per bottle, which is a different risk. 8 8 9 is it 50 percent of the batch? 9 One double-thick tablet in a bottle is 10 There were -- and I'm not an expert on 10 the medical equivalent of a patient accidentally 11 this, but they did a visual inspection of a batch of 11 taking a double daily dose. 3.4 million tablets and pulled out a couple dozen. 12 BY MR. DEAN: 12 13 I have no idea -- I'm starting to say, 13 Would you --O. what's the risk to a patient population of what the 14 14 I have no information on these A. percentage of that batch was that could have 15 15 statistical probabilities or on either plaintiffs' or 16 defendants' assessment of those issues. 16 potentially been double thick? 17 Because, to my assessment, the entire 17 Would you agree it would be a waste of batch was not submitted to a validated screening for 18 time to do signal detection for something that is 18 19 those double-thick tablets. 19 admittedly a red herring? 20 You already admitted that you're not an MR. THOMPSON: Object to the form. 20 expert in quality assurance or quality control; THE WITNESS: When was it determined to 21 21 correct? 22 be a red herring? 22 23 A. Yes, but I would have liked them to have 23 BY MR. DEAN: 24 sent me something that was quantitative. But there 24 Q. Well, sometime within the last year. If, indeed, it was a red herring, I 25 was nothing. 25 Page 119 Page 121 1 So you have an absence of information on 1 would agree with you. But the -- there is generally a 2 that issue: correct? 2 compulsive nature -- there is generally a compulsive 3 Yes. 3 nature to evaluating potential risk. A. MR. DEAN: Okay. Our videotape is 4 I have no information on potential 4 5 5 almost expired. versus actual risk, and I do not know at which time 6 Let's go off the record. 6 potential risk was abandoned. 7 VIDEO OPERATOR: Going off the video 7 The investigation of the double-thick 8 8 tablet from 2004 did not include analytics to allow record. 9 This is the end of Tape 2. 9 assessment of suprapotency or subpotent dose of The time is 12:03 p.m. 10 10 Digoxin. I was also not provided the routine Health (A luncheon recess was taken from 11 Hazard Assessment with that finding. 11 12 12:03 p.m. to 1:05 p.m.) 12 And let me be careful with this one, VIDEO OPERATOR: We're now back on the I've been trying to assess over the course of this 13 13 14 period if there's documentation of recurrence, what video record. 14 percentage of the batch, how is it distributed into 15 This is the start of Tape 3. 15 16 The time is 1:05 p.m. 16 the bottles, and all of that information has not been 17 BY MR. DEAN: 17 provided to me. I cannot say based on what's been You understand you're still under oath, 18 O. 18 Dr. Frank? 19 19 provided to me that there was no risk. 20 I -- I really need to be very careful A. 20 Dr. Frank, do you understand that the --21 21 because there's -- there's an absence of information that in this litigation a number of people are trying provided to me to be -- that I can independently 22 22 to recover money as the result of the injuries they 23 substantiate the risk of the double-thick tablets or 23 allege they received from taking Digitek tablets? 24 24 the blend issue, the period of time associated with 25 Do you understand that to be the 25 the risk or the magnitude of the risk.

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	Page 122		Page 124
1	underlying purpose of the litigation?	1	Google search, I was tempted to search the FDA web
2	A. Yes.	2	site. I did not.
3	Q. Okay. And do you understand do you	3	I left no Internet footprint of my
4	have an understanding as to whether the FDA has spoken	4	involvement in this case, other than the e-mail trail
5	on the issue of whether there was likely harm to	5	that the Miller firm and Motley Rice left.
6	consumers from Digitek?	6	Q. So you did no independent research on
7	A. Last night, Mr. Thompson read the press	7	your own, outside of that which you were provided, by
8	release to me. I am not privy to the FDA procedures	8	the plaintiffs' counsel; correct?
9	or the extent of the data mining that went on in order	9	A. No. I left nothing on the Google
10	to support that statement that there was no risk to	10	server.
11	public health.	11	Q. And so let me hand you we've been
12	My assumption, having been in the FDA,	12	talking about the FDA statement. It's what we marked
13	is that that statement would have been based on all of	13	as Plaintiff's Exhibit 38; correct?
14	the existing available data at that time.	14	A. Yes.
15	But having never worked in that division	15	Q. And this was issued in July of 2009;
16	of the FDA and having not been exposed to those	16	correct?
17	procedures, I cannot comment any further than to say I	17	A. Yes.
18	was read that press release.	18	Q. And so this would have been available
19	Q. Was that the answer you just gave me,	19	for to you if you had done what you refer to as a
20	was that the answer that you were instructed to give	20	Google search. If you had wanted to find this
21	last night by the plaintiff's counsel?	21	document, you could have easily found it. It's on the
22	A. No. In fact, I brought it up. And they	22	FDA web site; correct?
23	had asked me to be extremely cautious probing into	23	A. Yes. But given the privacy issues of
24	data mining issues.	24	the Google server, I did not do any research on
2.5	Q. Did you was that your first notice	25	Google.
		i	
	Page 123		Page 125
1	Page 123 about that FDA statement, last night?	1	Q. Given the privacy issues?
1 2	_	1 2	<ul><li>Q. Given the privacy issues?</li><li>A. I watch commentary TV occasionally, and</li></ul>
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32 (Pages 122 to 125)

	Page 126	_	Page 128
1	there for eternity and they data mine that aggregate	1	injured people; correct?
2	data.	2	A. Yes.
3	Q. Who does?	3	Q. Okay. And so one key question would be
4	A. Google.	4	did anyone ingest defectively manufactured Digitek,
5	Q. And what will they do with you were	5	that would be important in the litigation; correct?
6	afraid of what Google would do with it if you did an	6	A. Yes.
7	Internet search? Is that what you're telling me?	7	Q. Okay. And if they did, how much and
8	A. People can come to Google and get that	8	over what period of time, that would be another
9	data right now.	9	relevant question; right?
10	Q. And were you afraid of what they might	10	A. Yes.
11	do to you if you somebody might do to you if you	11	Q. Okay.
12	did an Internet search on an FDA web site? Is that	12	A. Wait. No, I hope I gave you the right
13	what you're telling me?	13	information about my electrical silence.
14	A. I made an extremely conservative	14	Q. Now
15	assumption that I was going to maintain electrical	15	A. I think it's irrelevant, but okay.
16	silence on this case for the most part.	16	Q. Now, the
17	I think the only thing I did was pull	17	MR. THOMPSON: It's the most that's
18	up here I need to qualify this, I do remember	18	the most eloquent opinion of big pharma that I've ever
19	pulling up Digoxin label. But I did not search	19	heard.
20	Digitek.	20	THE WITNESS: It's of Google, actually.
21	Q. Did the plaintiffs' lawyers instruct you	21	BY MR. DEAN:
22	not to go on the FDA web site to find relevant	22	Q. Now, you've had a chance to review
23	information about Digitek?	23	Exhibit 38 last night, I believe; correct?
24	A. No. I talked to them	24	A. Mr. Thompson read sections of it to me.
25	MR. THOMPSON: Object to the form.	25	Q. Oh, you have so you have just you
	Page 127		Page 129
1	THE WITNESS: I talked to them about the	1	haven't read the whole document then?
2	THE WITNESS: I talked to them about the electrical silence. I asked them not to send me	2	haven't read the whole document then?  A. No. I was told that I would probably be
2	THE WITNESS: I talked to them about the electrical silence. I asked them not to send me documents by e-mail. And I believe I told them	2 3	haven't read the whole document then?  A. No. I was told that I would probably be presented with this today.
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2 3 4 5 6	THE WITNESS: I talked to them about the electrical silence. I asked them not to send me documents by e-mail. And I believe I told them exactly what I was telling you.  And maybe it is completely irrelevant, but I had no idea of the impact. And I have to say,	2 3 4 5 6	haven't read the whole document then?  A. No. I was told that I would probably be presented with this today.  Q. What sections did Mr. Thompson read to you?  You don't have to read the words. Just
2 3 4 5 6 7	THE WITNESS: I talked to them about the electrical silence. I asked them not to send me documents by e-mail. And I believe I told them exactly what I was telling you.  And maybe it is completely irrelevant, but I had no idea of the impact. And I have to say, I'll modify it, I do remember going on for one drug	2 3 4 5 6 7	haven't read the whole document then?  A. No. I was told that I would probably be presented with this today.  Q. What sections did Mr. Thompson read to you?  You don't have to read the words. Just tell me the section.
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Videotaped

	Page 130		Page 132
1	for 505(b).	1	A. I would think they would be extremely
2	But I'm also aware of cases where	2	cautious in their public statements given the fact
3	generic manufacturing has been of variable quality and	3	that, my understanding, there was a Congressional
4	it has impacted clinical outcomes.	4	inquiry on this. I think that these statements have
5	Q. Let me stop you. I want you to, if you	5	probably been very carefully worded.
6	can, answer my question.	6	Q. So you have no basis my question is,
7	And that is, what what parts of	7	you have no basis to disagree with that sentence, do
8	Exhibit 38 did Mr. Thompson call to your attention	8	you?
9	last night?	9	A. No.
10	Did you see it last night or did he just	10	Q. Then the next sentence says, In our best
11	read parts of it to you?	11	judgment, given the very small number of defective
12	A. He read it. And when he read me, I was	12	tablets that may have reached the market and the lack
13	actually worrying about certain things I was going to	13	of reported adverse events before the recall, harm to
14	say today. So if he said something and it would	14	patients was very unlikely.
15	trigger thoughts and I had lapses of attention while	15	Did I read that correctly?
16	he was reading.	16	A. Yes.
17	Q. Well, sometimes that happens to	17	Q. Do you have any basis to disagree with
18	Mr. Thompson.	18	the FDA's public statement in that sentence?
19	A. No. It happens to me a lot because if	19	A. No. I do recall this being read. At
20	you say something to me and it kicks off a trigger	20	the time we were trying to access the other documents
21	thought, I will follow it and then I'll come back, and	21	on his computer. That's what distracted me.
22	that's why I have you clarify things.	22	I'm trying to remember how this occurred
23	Q. Seriously, you said he made reference to	23	because we were trying to bring in other documents all
24	a couple points.	24	at one time. And I made the statement that, yes, they
25	Have you ever read this document before	25	said harm to patients would be very unlikely.
	Page 131		Page 133
1	Page 131 now?	1	And that's where I brought up that you
2	now? A. No.	2	And that's where I brought up that you would assume that they would have examined all
2	now? A. No. Q. Before right now?	2 3	And that's where I brought up that you would assume that they would have examined all available data at the time they made that statement.
2 3 4	now? A. No. Q. Before right now? A. No.	2 3 4	And that's where I brought up that you would assume that they would have examined all available data at the time they made that statement.  Because to have made that statement
2 3 4 5	now? A. No. Q. Before right now? A. No. Q. So this, as you're sitting here right	2 3 4 5	And that's where I brought up that you would assume that they would have examined all available data at the time they made that statement.  Because to have made that statement without examining all available data would have left
2 3 4 5 6	now?  A. No. Q. Before right now? A. No. Q. So this, as you're sitting here right now, is the first time you've actually seen Exhibit	2 3 4 5 6	And that's where I brought up that you would assume that they would have examined all available data at the time they made that statement.  Because to have made that statement without examining all available data would have left them open to criticism had they been called before
2 3 4 5 6 7	now?  A. No. Q. Before right now? A. No. Q. So this, as you're sitting here right now, is the first time you've actually seen Exhibit 38; is that correct?	2 3 4 5 6 7	And that's where I brought up that you would assume that they would have examined all available data at the time they made that statement.  Because to have made that statement without examining all available data would have left them open to criticism had they been called before Congress.
2 3 4 5 6 7 8	now?  A. No. Q. Before right now? A. No. Q. So this, as you're sitting here right now, is the first time you've actually seen Exhibit 38; is that correct? A. Yes.	2 3 4 5 6 7 8	And that's where I brought up that you would assume that they would have examined all available data at the time they made that statement.  Because to have made that statement without examining all available data would have left them open to criticism had they been called before Congress.  Q. So you assume that they did examine that
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Page 134	Page 136
1 issue a clinical hold letter. 1 the signal would have b	een valuable. I think there is
	of my work versus the scope of
	of my work versus the scope of
	the signal has to do with
	the signal has to do with
	tual risk or any potential
	But I didn't do the medical
7 they looked at before they made this statement was the 7 evaluation or signal dete	
8 reported Adverse Event Reports before the recall; 8 I'm formulating	1
	was asked to address, I would
	nk like a medical officer
	ecame disconcerting issues to
12 Q. So they had access to information that 12 me.	
	at I was not given
<b>↓</b>	e else may have and I didn't have
15 A. Yes. 15 a fuller picture, and also	
16 Q. Okay. So this document, you would 16 definitive evidence of the	
	eally no way to ever really
18 site? 18 know how much of thos	se lots was affected, it left a
19 A. Where's the post date?	
20 MR. THOMPSON: I object to the form of 20 So that it became	ne theoretical detection
21 that question. I'm not sure how we know that. 21 of risk. Did they look?	Did they have procedures in
22 THE WITNESS: I can't find the posting 22 place and in use? Were	they documented? Were they
23 date. 23 affected by coding issue	es?
24 BY MR. DEAN: 24 Because I had n	o idea what was actually
25 Q. Do you know do have any knowledge as 25 out there to be detected	or the things that had been
Page 135	Page 137
1 to when this was posted? 1 written and been provide	ded to Dr. Leikin or to the
2 A. Not unless it is on this I can't I 2 other expert witnesses.	
3 can't see the official date on this posting 3 BY MR. DEAN:	
4 Q. Okay. 4 Q. Let's go back.	
,	ree that in the statement
	ear that the FDA looked at
,	ion with regard to Digitek;
8 Q. Do you know whether it's still on their 8 correct?	
2. 20 ) 0. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2.	on is that there was a data
10 A. Well, the date it was printed was June 10 analysis behind that sta	
, , , , , , , , , , , , , , , , , , ,	have permitted the FDA, at
12 Q. So you assume it's still there; 12 least they relied, at le	-
	their conclusion; correct?
14 A. Yes. Uh-huh. 14 A. Yes.	
=	SON: I object to the form of
	.c. i coject to the total of
16 Q. No. I'm waiting for me myself. I'm 16 that question.  17 waiting to formulate a question. So don't feel 17 BY MR. DEAN:	
'	tence contained within this
	ı
, , , , , , , , , , , , , , , , , , ,	
19 Would you agree this information about 19 document would have p	·
Would you agree this information about 19 document would have put the FDA looking at Adverse Event Reports on Digitek 20 you in regard to formulation.	ating your pharmacovigilance
Would you agree this information about 19 document would have put the FDA looking at Adverse Event Reports on Digitek 20 you in regard to formulate 21 before the recall would have been relevant information 21 opinions, wouldn't it?	·
Would you agree this information about 19 document would have put the FDA looking at Adverse Event Reports on Digitek 20 you in regard to formul 21 before the recall would have been relevant information 21 opinions, wouldn't it? 22 to you in reaching issues of signal in commenting 22 A. Yes. And	ating your pharmacovigilance
19 Would you agree this information about 20 the FDA looking at Adverse Event Reports on Digitek 21 before the recall would have been relevant information 22 to you in reaching issues of signal in commenting 23 upon issues of signal detection?  19 document would have p 20 you in regard to formul 21 opinions, wouldn't it? 22 A. Yes. And 23 Q. And the plain	ating your pharmacovigilance
Would you agree this information about the FDA looking at Adverse Event Reports on Digitek before the recall would have been relevant information to you in reaching issues of signal in commenting upon issues of signal detection?  MR. THOMPSON: Object to the form.	ating your pharmacovigilance

35 (Pages 134 to 137)

Videotaped

1			
	Page 138		Page 140
1	charge that you were given to answer, did they?	1	those two stray cases on the total signal detection.
2	MR. THOMPSON: Object to the form.	2	The FDA says the lack of reported
3	THE WITNESS: I was not provided any of	3	events. These older drugs that have had long market
4	the documentation that you are referring to.	4	exposure and very little novel adverse events often
5	BY MR. DEAN:	5	have underreporting.
6	Q. And you were not provided with Exhibit	6	And when you do the signal detection,
7	38, were you?	7	you actually do it on the generic version, even when
8	A. No. And I did not independently look	8	you're doing it on the branded compound, because
9	for it, and I hope that I was not lapse lax in	9	people just report the drug.
10	trying to seek it independently.	10	Q. If you let me interrupt you.
11	Q. Is this the kind of information in	11	If you were doing signal detection for a
12	Exhibit 38 that you referred to before as white space?	12	manufacturing defect, you'd only do it on the product
13	A. It's a little bit out of the white	13	that was manufactured by a given manufacturer;
14	space, but it is white space for me now that you	14	correct?
15	brought it in. The truth of the matter is, the fact	15	A. But the reports are often silent from
16	that I did not put this in context by going out and	16	that and that has to be taken into account very
17	looking, I allowed that white space to occur.	17	carefully, because you don't want to do an inadequate
18	And I did it after discussing I	18	document to be presented in this type of scenario.
19	believe that I discussed this Google issue over lunch	19	Q. Would you agree if you're trying to do
20	with them.	20	signal detection to spot a manufacturing defect, you
21	I don't know whether it was seen as	21	would look to the product manufactured by that
22	important, but we sort of agreed that the best way to	22	particular manufacturer?
23	transfer information was either in paper or	23	A. When you have the information. But if
24	electronically.	24	the reports were silent, the default is to include
25	And they never asked me to go out and	25	them rather than to omit them.
	Page 139		Page 141
,	_		,
1		1 1	O There's no question pending
	look for additional information. They provided it to	1	Q. There was another point I wanted to
2	me. So I'm giving you the best of my recollection how	2	A. There was another point I wanted to
2 3	me. So I'm giving you the best of my recollection how this occurred.	2 3	A. There was another point I wanted to make:
2 3 4	me. So I'm giving you the best of my recollection how this occurred.  Q. The FDA did not say in here that the	2 3 4	A. There was another point I wanted to make.  Q. Why don't you let me formulate another
2 3 4 5	me. So I'm giving you the best of my recollection how this occurred.  Q. The FDA did not say in here that the adverse event reporting procedures of Actavis were	2 3 4 5	A. There was another point I wanted to make Q. Why don't you let me formulate another question.
2 3 4 5 6	me. So I'm giving you the best of my recollection how this occurred.  Q. The FDA did not say in here that the adverse event reporting procedures of Actavis were inadequate for them to form an opinion about the	2 3 4 5 6	A. There was another point I wanted to make.  Q. Why don't you let me formulate another question.  A. Okay.
2 3 4 5 6 7	me. So I'm giving you the best of my recollection how this occurred.  Q. The FDA did not say in here that the adverse event reporting procedures of Actavis were inadequate for them to form an opinion about the likelihood of injury to consumers, did they?	2 3 4 5 6 7	<ul> <li>A. There was another point I wanted to make.</li> <li>Q. Why don't you let me formulate another question.</li> <li>A. Okay.</li> <li>Q. Does Exhibit 38 help you fill the void</li> </ul>
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Videotaped

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Page 142
                                                                                                               Page 144
                                                                               MR. DEAN: Excuse me. Could -- could
      make an explicit statement of the impact. I'm sure
                                                                 1
 1
                                                                 2
                                                                      you just read back my question and the answer.
 2
      they were very careful about the wording.
                                                                 3
 3
               But I have no information that would
                                                                              (The court reporter read back the
 4
                                                                 4
                                                                      following:
      tell me -- I may need to talk to Mr. Thompson before I
 5
                                                                 5
                                                                               "QUESTION: Do you think the FDA would
      completely elucidate this, because I told him -- he
      asked me not to digress into this area, that it was
 6
                                                                 6
                                                                      have issued this statement unless they were satisfied
                                                                      with the reporting procedures of Actavis in regard to
                                                                 7
 7
      outside of my scope.
 8
                                                                 8
                                                                      Digitek? Yes or no?"
              And either I should be silent or I
                                                                 9
                                                                               "ANSWER: I think the answer is yes,
 9
      should speak to him before I completely comment on --
10
                                                                10
                                                                      but --")
      on this.
                                                                              THE WITNESS: I believe that the FDA was
                                                               11
11
      BY MR. DEAN:
12
               Well, that's not --
                                                               12
                                                                      very, very careful to take into account the impact of
         O.
                                                               13
                                                                      compliance with reporting procedures by Actavis at the
13
         A.
               It's not permissible?
                                                                      time they issued that statement.
14
          Q.
                With the background you've given us, I
                                                               14
                                                               15
                                                                      BY MR. DEAN:
15
      don't think that's an appropriate conversation for --
      to be had at this point. I think you need to answer
                                                               16
                                                                                And would you agree that if they had
16
                                                                      been satisfied with those procedures, they would not
                                                               17
17
      my question.
18
                Okay. I have not been provided any
                                                               18
                                                                      have issued the statement?
         A.
                                                               19
                                                                               I'm going to say yes, but I really don't
19
      information that says that there was an investigation
                                                                          A.
20
      after the consent decree where anyone went in and data
                                                               20
                                                                      know.
21
      mined the Actavis database.
                                                               21
                                                                          O.
                                                                               Okay. Thank you.
22
              There's two ways to look at it, what
                                                               22
                                                                               Now, you -- a few minutes ago, you
                                                               23
                                                                      talked -- you talked -- you mentioned some product
23
      events are coded.
                                                                      that was incinerated. What did you have reference to?
24
              Because at the time of the 2008
                                                               24
                                                                25
                                                                               MR. THOMPSON: Mr. Dean, are you -- are
25
      inspection, there's still investigator observations of
                                                                                                               Page 145
                                               Page 143
                                                                 1
                                                                      we through with Exhibit 38?
 1
      unreported serious cases and there's a statement made
                                                                 2
                                                                              MR. DEAN: I think we are, Mr. Thompson.
 2
      by one of the employees about submitting cases from
                                                                 3
                                                                              MR. THOMPSON: So you're not going to
 3
      2006.
                                                                      question her on the other four bullet points under
 4
              Now, the remediation is outlined in the
                                                                 4
                                                                 5
                                                                      that paragraph; is that right?
 5
      correspondence, including the PSURs for aggregate
 6
                                                                 6
                                                                              MR. KAPLAN: Well, I'm going to object
      reporting. And the comment by the company employee
 7
                                                                 7
                                                                      to counsel making statements or inquiries here.
      talked about how far back they would go.
                                                                 8
 8
                                                                      That's entirely inappropriate.
              In other words, they didn't want to go
 9
      back before the acquisition. And I have no way to
                                                                 9
                                                                              I move that that be stricken.
10
                                                               10
                                                                              MR. THOMPSON: All right. Well, let me
      completely put that in context.
11
              So there's no data mining -- there's two
                                                               11
                                                                      then make --
                                                               12
                                                                              MR. KAPLAN: This is an examination by
12
      ways to data mine. One is the coded cases and the
                                                                      Mr. Dean. He can ask whatever questions he wants and
                                                               13
13
      other is to say the coding is defective, we're going
                                                                      it's just inappropriate for you to comment.
14
                                                               14
      to text search the narratives.
                                                               15
                                                                              If you do any more commenting, we're
15
               And what if the narratives are only 50
                                                                      going to be talking to Judge Goodwin about that.
16
      percent coded? There could be undetected signal.
                                                               16
                                                                              MR. THOMPSON: All right.
                                                               17
17
              And in this case, it's unlike some of
18
      the other cases I've heard of where they have done
                                                                18
                                                                              Let's talk to Judge Goodwin about the
19
                                                               19
                                                                      presentation of Defendant's Exhibit to my expert and
      those investigations. So I don't know how to comment
                                                                      intimating that this was withheld from her, when, in
20
                                                               20
      to you.
                                                               21
                                                                      fact, this is a document that was withheld from us
                Do you think the FDA would have issued
21
          Q.
                                                                      until last week when it was delivered to us from
22
      this statement unless they were satisfied with the
                                                               22
                                                                      Mr. Anderton, who indicated that he had given it to
23
      reporting procedures of Actavis in regard to Digitek?
                                                               23
                                                                      his expert, but it had not been produced to us.
                                                               24
24
       Yes or no?
                                                               25
                                                                              MR. DEAN: This is not a company
25
               I think the answer is yes, but --
          A.
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Videotaped

	Page 146		Page 148
. 1	document. We're not we can have this discussion	1	Do you have Exhibit 261 in front of you,
2	MR. THOMPSON: Well, your testimony	2	Dr. Frank?
3	your testimony to her has begun to intimate that the	3	A. Yes.
4	plaintiffs' counsel has done this and done that.	4	Q. Good. Let's see if I do.
5	And, in fact, I'm looking at a document	5	All right. I'm on Page 4, which is the
ļ	that you've confronted her with which was never	6	first page of are you with me there? And it's in
6	produced to us in regular time and which was never	7	the section on Background.
7	available to be sent to her.	8	A. Yes.
8	MR. DEAN: Never available to be sent to	9	Q. I want to direct your attention to the
9	her because it was on the FDA web site?	10	second paragraph.
10		11	A. Uh-huh.
11	BY MR. DEAN:	12	Q. You reference PSUR preparation; right?
12	Q. Let's go back to the question that I	13	
13	just asked you about. You, a few minutes ago, used	14	
14	the word "incinerated," I think; is that correct?		· - ·
15	A. I will tell you the information, and I	15	question: Does a generic manufacturer who distributes
16	don't it's probably in here. It may not be. But	16	product only in the United States have any duty to
17	in the recall packet, they have forms to fill out to	17	submit PSURs?
18	send the recalled product to Minnesota for	18	A. Their legal obligation is U.S. Periodic
19	destruction. We can pull that out.	19	Reports. But the FDA accepts PSURs in lieu of the
20	My impression, and I am willing to be	20	U.S. Periodic Reports for the aggregate reporting.
21	corrected if I am wrong, is that there was no	21	So many companies that operate globally
22	analytical work done on that recalled product before	22	produce one PSUR and then it is modified with
23	it was incinerated.	23	appendices for country-specific reporting
24	Q. So you're talking about when you say	24	requirements.
25	"recalled product," you're speaking about the recalled	25	Q. Would you agree that if a any drug
	D = 147	l	
	Page 147		Page 149
1		1	Page 149 manufacturer, brand name or generic, only distributes
1 2	Digitek in 2008; correct?	1 2	
	Digitek in 2008; correct?  A. I think it went from June 6, 2006	i	manufacturer, brand name or generic, only distributes
2	Digitek in 2008; correct?  A. I think it went from June 6, 2006 through 2008.	2	manufacturer, brand name or generic, only distributes product in the United States, they do not have to
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2 3 4 5	Digitek in 2008; correct?  A. I think it went from June 6, 2006 through 2008.  Q. Right.  It was announced in 2008, but going back for a couple years. So that that's fair. So that	2 3 4 5	manufacturer, brand name or generic, only distributes product in the United States, they do not have to submit a PSUR, do they?  A. No. If it's just U.S., it can be just a U.S. Periodic Report.  Q. Thank you.  Now, in the third paragraph, you've got
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Digitek in 2008; correct?  A. I think it went from June 6, 2006 through 2008.  Q. Right.  It was announced in 2008, but going back for a couple years. So that — that's fair. So that was the time of the — the product that first went on the market in 2006, some of that was recalled.  But your testimony is that when that product got recalled, you believe that product was incinerated; correct?  A. This is why I did this document. I wanted to be very, very careful. I have a fixed idea in my mind from reviewing the documents that this occurred. If I am wrong, I will stand corrected.  Q. Well, what is your understanding as to how much of the product was incinerated?  A. I don't know. I was — it may be a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	manufacturer, brand name or generic, only distributes product in the United States, they do not have to submit a PSUR, do they?  A. No. If it's just U.S., it can be just a U.S. Periodic Report.  Q. Thank you.  Now, in the third paragraph, you've got some information regarding the company history, do you not?  A. Yes.  Q. Where did that come from?  A. It was abstracted from the Establishment Inspection Reports and from the company correspondence to the FDA, which is where I found the dates, the consent decrees, the day it was the defect was lifted in 2001, the dates of the acquisition.  All of this was taken and it should go
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Videotaped

	Page 150		Page 152
1	question, please.	1	would if I needed, I would ask for more information
2	In the fifth paragraph, the one that	2	to cover that period.
3	starts, There is little or no information, I take it	3	Q. And where did you get the information
4	that you were provided no information about either	4	that such an inspection took place?
5	Amide or Actavis well, actually, you had the	5	A. I can find it for you. Because this was
6	information about the 2004 incident; right?	6	a later edition, and I believe, and I might have to go
7	A. Yes.	7	back and verify, that it came out of this, the
8	Q. So	8	introduction of this Establishment Inspection Report.
9	A. That was provided yeah, that was	9	Q. That's Plaintiff's Exhibit 91, for the
10	I'm not sure when it was when I wrote that, but,	10	record.
11	yes, there was the information became more	11	A. I had to go through the eyes of the FDA
12	intensive starting with this February 2006 inspection.	12	inspectors to find things that I was not provided.
13	Q. So is it fair to say you have no	13	And there were some very good historical summaries.
14	information before February 2006 about what might be	14	Q. Here's my question for you.
15	termed alleged deficiencies in adverse event	15	If you can find it quickly, that's fine,
16	reporting? Is that fair?	16	but that's a long document. I'm ready to go on to
17	A. If you look at the timeline, the first	17	another question if you can't find it.
.18	inspection I was able to identify where I don't have	18	A. Okay.
19	the 483s or the reports was in Elizabeth, New Jersey,	19	Q. Are you ready to go on?
20	August 11th, '03 to August 14th, '03.	20	A. Yes.
21	It was specifically a post-marketing	21	Q. Here's my simple question to you: On
22	adverse drug experience inspection, and it was	22	this, what you've labeled Inspection 1, Elizabeth, New
23	classified as NAI.	23	Jersey, in 2003, do you know whether that referred
24	Q. And what does that mean?	24	that that was a inspection relating to Digitek or to
25	A. No action indicated.	25	totally different product lines?
	Page 151		Page 153
1	Q. And do you believe that what you've	1	Do you know?
1 2	Q. And do you believe that what you've marked as Exhibit I'm sorry it's what is	2	Do you know? A. No.
	Q. And do you believe that what you've marked as Exhibit I'm sorry it's what is referenced as Inspection 1 related to a company called	2 3	Do you know? A. No. Q. Okay.
2 3 4	Q. And do you believe that what you've marked as Exhibit I'm sorry it's what is referenced as Inspection 1 related to a company called Amide or related to another company or related to a	2 3 4	Do you know? A. No. Q. Okay. A. Any
2 3 4 5	Q. And do you believe that what you've marked as Exhibit I'm sorry it's what is referenced as Inspection 1 related to a company called Amide or related to another company or related to a company that was operating in Elizabeth, New Jersey?	2 3 4 5	Do you know? A. No. Q. Okay. A. Any Q. Okay. You don't; right?
2 3 4 5 6	Q. And do you believe that what you've marked as Exhibit I'm sorry it's what is referenced as Inspection 1 related to a company called Amide or related to another company or related to a company that was operating in Elizabeth, New Jersey?  A. No. It came from one of these documents	2 3 4 5 6	Do you know?  A. No. Q. Okay. A. Any Q. Okay. You don't; right? A. No.
2 3 4 5 6 7	Q. And do you believe that what you've marked as Exhibit I'm sorry it's what is referenced as Inspection 1 related to a company called Amide or related to another company or related to a company that was operating in Elizabeth, New Jersey?  A. No. It came from one of these documents that was either an FDA inspection of Amide or one of	2 3 4 5 6 7	Do you know?  A. No. Q. Okay. A. Any Q. Okay. You don't; right? A. No. Q. Let's just leave it at that, I'll go on
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	Page 154		Page 156
1	Did you ask for the documentation, the	1	best recollection?
2	backup on that? Did you ask for it?	2	Q. First of all, do you know?
3	A. I talked to Pete Miller about this on	3	A. I believe this came from the Amide
4	June 2nd.	4	response immediately following the 2006 inspection.
5	Q. Did you ask him for it?	5	And the FDA responses reiterated concern with serious
6	A. Yes.	6	underlying systemic issues.
7	Q. Did you get it?	7	But I can't recall the FDA ever
8	A. They were not aware of any MHRA	8	responding to this particular MHRA inspection.
9	inspection reports in the discovery. I think, if I'm	9	And I inquired whether Digitek was
10	not mistaken, there may have been others.	10	marketed outside of the U.S. and the potential impact
11	The fact that there was an MHRA	11	of the MHRA inspection on collection of Digitek cases,
12	inspection in 2005 implies a repeat inspection in a	12	per se.
13	two-year cycle. But that's an assumption.	13	And, to my knowledge, and to the
14	But, no, I have no information about	14	knowledge of all the counsel that I had, Digitek is
15	MHRA inspection findings other than the fact that one	15	only marketed in the U.S. And so the transfer of
16	of those was detected at the time of the due diligence	16	these cases from Copenhagen to the U.S. did not impact
17	in the acquisition, and the decision was made to	17	compliance with Digitek or signal detection.
18	implement the agreement between Amide and the MHRA	18	Q. Did you put that in your report?
19	after the merger in March.	19	You didn't put that in your report, did
20	And there was FDA inspection findings of	20	you?
21	this noncompliance that sort of coincided with them.	21	A. No. It was verbal communication.
22	Q. Did you understand this to be a first	22	Q. Wouldn't a fair and objective expert
23	of all, MHRA is a European regulatory agency; correct?	23	witness have noted in a Digitek case that an
24	A. Yes.	24	observation about an MHRA inspection didn't have
25	Q. Did you understand this did you	25	anything to do with Digitek?
	Page 155		Page 157
1	understand this reference to the MHRA inspection to	1	MR. THOMPSON: Object to the form.
2	deal with a reporting issue as a result of corporate	l	· · · · · · · · · · · · · · · · · · ·
	deal with a reporting issue as a result of corporate	1 2	THE WITNESS: Possibly, If I do it
	acquisitions?	2	THE WITNESS: Possibly. If I do it
3	acquisitions?	3	again, I'll be more careful with the annotation. I
3 4	A. No. But the MHRA	1	again, I'll be more careful with the annotation. I would say
3 4 5	A. No. But the MHRA Q. You did not; is that right?	3 4	again, I'll be more careful with the annotation. I would say BY MR. DEAN:
3 4 5 6	<ul><li>A. No. But the MHRA</li><li>Q. You did not; is that right?</li><li>A. No. This was this was before the</li></ul>	3 4 5	again, I'll be more careful with the annotation. I would say BY MR. DEAN: Q. But you do agree that, as you understand
3 4 5 6 7	<ul> <li>A. No. But the MHRA</li> <li>Q. You did not; is that right?</li> <li>A. No. This was this was before the acquisition.</li> </ul>	3 4 5 . 6	again, I'll be more careful with the annotation. I would say BY MR. DEAN: Q. But you do agree that, as you understand the facts now, that Digitek would not have been
3 4 5 6 7 8	<ul> <li>A. No. But the MHRA</li> <li>Q. You did not; is that right?</li> <li>A. No. This was this was before the acquisition.</li> <li>It was independent, and it was I</li> </ul>	3 4 5 6 7	again, I'll be more careful with the annotation. I would say BY MR. DEAN: Q. But you do agree that, as you understand
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Videotaped

June 30, 2010

#### Page 158 Page 160 1 But they -- the reason this is in there satisfaction with this MHRA inspection? 1 2 is they warned the company that these specific 2 Are you aware of the final word on that 3 violations are serious and they may be symptomatic of 3 from the FDA? 4 underlying problems. 4 A. The implementation of this agreement with the MHRA was effective on March 1st. And for 5 And I was asked to assess systemic 5 issues. And I wasn't given any Digitek subsets, so I reasons unknown to me, Copenhagen sent a batch of 6 6 7 started pulling in a lot of things, like MHRA 7 cases two to three months later, and it's in one of inspections. But the FDA gave them warning. 8 8 the response letters. 9 And I started looking for has anybody 9 They made a decision and wrote a note to 10 given me evidence of the compliance remediation plan, the file to call their initial receipt date the day 10 the tracking of it with Metrix, and its adequacy. they got these from Copenhagen, rather than the date 11 11 So this is put in here because the FDA 12 12 they were first received in Copenhagen. 13 warned that they needed to assess broader systemic And the FDA made an observation of that 13 14 and required the company to make a change, and there's 14 issues. a note to the file of the change in that process. 15 Q. So at this point, as you read that set 15 16 of correspondence, as a pharmacovigilance expert, you 16 But they made an -- they made a decision, and I don't know who ratified it, who was have a concern that they may not have engaged in the 17 17 right corrective procedures; correct? 18 18 given the governance, but the ineffective implementation or somehow the delay in this 19 Or else I was not given the documents. 19 Because they produced a QSIP, and it's huge, and they 20 20 implementation led to further FDA inspection findings. said they'd send it to me, that I could look at it. Because the transfer did not occur 21 21 immediately at March 1st. The first transfer was a 22 Q. Who said that? 22 23 Pete Miller did. 23 batch a couple of months later and led to A. But you -- did you request it? 24 Q. 24 noncompliance. That's sort of why I left it in. 25 25 But my question to you is, do you know A. Page 159 Page 161 1 Q. Did he send it to you? the final resolution of this in the eyes of the FDA? 1 2 A. No. It was inspection finding that required 2 3 Okay. Now, isn't it -- when you see a 3 remediation, and I do not recall any inspectors 4 history of 483s and warning letters like this, isn't assessing the adequacy of the corrective action. 4 it usual for the FDA at the end of the day, at the end 5 5 Let's turn to Page 5. The second of the sequence, to tell the company whether they've paragraph on Page 5 you recite the history of the 6 6 satisfactorily engaged in corrective procedures or warning letters and the responses. 7 7 8 whether they're still deficient? 8 Well, there was a 483 and a response and 9 Isn't that commonplace? 9 a warning letter and a response and you recite all The FDA revised warning letter, I think 10 10 that history, do you not? this was in July, reiterates the findings, talks about 11 11 Second paragraph, Page 5? A. the inadequacy of the response, and this is a quote. 12 12 Page 5. Q. Now, my question is, did the company 13 13 A. Yes. engage in any type of root cause analysis or process And did you -- you've talked before 14 14 Q. evaluation to assess broader systemic issues, and did 15 15 about white spaces. Is there a white space in this they put in place a remediation program that was 16 16 paragraph where there is, in all likelihood, a missing adequately implemented and tracked. 17 17 document? The bottom line that I came to based on 18 I documented the missing letters. But 18 A. 19 what I could see is they had similar repeat inspection 19 it's not -- I don't know that I translated the findings in 2008, there was a statement that one of 20 documented missing letters in here into the 20 the company -- and it was Mr. Delicato, about cases in 21 21 conclusion. 2005, which I thought were part of this remediation. 22 22 This -- this paragraph, there were And I don't know all the circumstances 23 23 issues with the accuracy of the responses from about this or the negotiations or what would be February 28th and February 8th, and the FDA took 24 24 submitted, but the white spaces, what they did, what 25 issues with those. 25

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	Page 162		Page 164
1	they did in the QSIP, but the outcome was the FDA said	1	(Witness reviews document.) Okay.
2	there's a total failure for quality systems.	2	They
3	There's still repeat pharmacovigilance	3	Q. You've never seen this document before,
4	findings.	4	have you?
. 5	And then when the recall occurred	5	A. No.
6	O. Who said there was a total failure of	6	Q. And we can agree that it is a letter
7	a total failure of what?	7	from the FDA to Actavis Totowa dated January 3, 2007;
8	A. That's a quote, and that might be	8	correct?
9	Q. That's a quote from who?	9	A. Yes. And I don't have this in the white
10	A. An FDA inspector in either the closeout	10	space, so I have no indication this letter existed
11	meeting or in this EIR. And because this is a	11	until you just gave this to me.
12	verbatim	12	Q. This is the first time you've ever seen
13	Q. And, in fairness, that was a quote about	13	it in your life and the first time you're even aware
14	total failure of quality control in regard to quality	14	of its existence; correct?
15	control, not in regard to pharmacovigilance. Do you	15	A. Yes.
16	agree?	16	Q. And we would agree that it says, in the
17	A. I was unable to sort out the quality	17	second paragraph, New Jersey District has reviewed
18	unit. It for the most part, it was addressing	18	your response regarding adverse drug experience
19	manufacturing issues.	19	reporting deficiencies. Your corrective action and
20	But my question is, there's usually	20	the revised procedures appear to be satisfactory.
21	quality systems that control pharmacovigilance quality	21	That's what it says; correct?
22	and product complaint and clinical research.	22	A. Absolutely.
2.3	There should have been some sort of a	23	MR. THOMPSON: I object to taking that
24	quality system for all of these business critical	24	out of context.
25	functions.	25	BY MR. DEAN:
	Page 163		Page 165
1	Q. Can we agree that if there is a letter	1	Q. So the in your paragraph on Page 5,
2	from the FDA to Actavis saying that they were	2	you referenced the 483s and the warning letters on the
3	satisfied with the company response to the	3	pharmacovigilance issues, but you didn't reference
4	pharmacovigilance issues contained in the warning	4	Exhibit 87 because you were unaware of it; correct?
5	letter of August 15, 2006, you've never seen it, have	5	A. Yes. I expressed concerns multiple
6	you?	6	times about missing information like this that could
7	A. No. I've not I did not see I did	7	impact on my
8	not identify in my review any interim FDA	8	Q. And it's clear that the FDA was
9	communication that said they were satisfied. If it's	9	satisfied with that response, wasn't it?
10	my error, I stand corrected. There are letters that I	10	MR. THOMPSON: Object to the form of the
11	was not provided, and I documented that.	11	question.
12	Q. Did you how did you document what you	12	THE WITNESS: Well, the FDA is
13	were not provided? How would you know how to document	13	satisfied. I don't know August 15th. Revised
14	it?	14	warning letter.
15	A. Oh, boy. I laid out this timeline for	15	Wait a second.
16	myself. Inspections I found are in red. Any	16	We acknowledge dated September 6th, the
17	information I have on the inspections was there unless	17	company responds, the procedures, I don't have October
18	there was a full report.	18	26th. There is a clear statement that corrective
19	In blue were the company's responses.	19	actions and the revised procedures were satisfactory.
20	And the black are these intercurrent communications.	20	BY MR. DEAN:
	And here in the timeline is part of my attempt to	21	Q. And you don't have any basis to disagree
21			
22	document things that were not included to me.	22	with the FDA position on that, do you?
22 23	document things that were not included to me.  Q. Let me hand you what we marked as	23	A. The company
22	document things that were not included to me.		- 1

	Page 166		Page 168
1	THE WITNESS: I do not believe I've seen	1	MR. DEAN: Do you want to keep going or
2	the additional revised procedures on October 25th, and	2	do you want to take a short break?
3	so I cannot make an independent determination.	3	MR. THOMPSON: I think we ought to take
4	And in order to really give you an	4	a break as we go, you know.
5	accurate opinion, I should probably read re-read	5 ·	MR. DEAN: I think we've been going
6	the September 6th.	6	about an hour. Let's take a short break.
7	However, I think that in a court of law,	7	I don't want to take a long one.
8	this FDA opinion would supersede my opinion unless I	8	MR. THOMPSON: Sure.
9	could really provide evidence to the contrary.	9	MR. DEAN: Let's go off the record.
10	BY MR. DEAN:	10	VIDEO OPERATOR: Going off the video
11	Q. Thank you.	11	record.
12	So as of January 3, 2007, we can agree	12	The time is 2:06 p.m.
13	that the FDA was satisfied it had received all adverse	13	(A recess was taken from 2:06 p.m. to
14	reaction reporting from Amide or for Actavis Totowa	14	2:16 p.m.)
15	that had been raised by the 483 and the warning	15	VIDEO OPERATOR: We are now back on the
16	letter; correct?	16	video record.
17	MR. THOMPSON: I object to the form of	17	This is the start of Tape 4.
18	the question and I entreat Dr. French (sic) to please	18	The time is 2:16 p.m.
19	read the entire document before she answers a single	19	BY MR. DEAN:
20	out-of-context sentence.	20	Q. Dr. Frank, in regard to Exhibit 87,
21	MR. DEAN: It's Dr. Frank, I believe.	21	we've before we broke, you agreed that this
22	MR. THOMPSON: I then I've just	22	provided relevant information on the status of the
23	I'm probably in the wrong place at the wrong time.	23	adverse event reporting at Actavis; correct?
24	THE WITNESS: This is very, very	24	MR. THOMPSON: Object to the form.
25	difficult because these corrective actions have a	25	THE WITNESS: I think it's an important
	Page 167		Page 169
1	scope. And I'm reading this out of context in the	1	piece of information that I would have liked to have
2	scope, so I can't track what the corrective actions	2	had when I when I came up with the conclusion.
3	were or the procedures.	3	I'd like to put it in context with the
4	And I have no information about the	4	decision to move pharmacovigilance from Totowa to
5	adequacy of the corrective actions during the future	5	Elizabeth, because Elizabeth apparently was compliant.
6	inspection because there's both the plan and the	6	Remember I told you about that NAI
7	implementation of the plan.	7	inspection. It's a very, very important piece of
8	So this is basically saying they did	8	information that could it clearly has a material
9	they did a corrective action. And the District Office	9	impact on the analysis. I cannot immediately put it
10	found it satisfactory, and I'm assuming that they	10	in context with the overall picture.
11	could implement it without revision.	11	I'm assuming that you're going to
12	BY MR. DEAN:	12	continue to present me with further information that's
13	Q. Earlier, much earlier this morning, you	13	extremely important to the assessment. But I do not
14	told us that what you were relying on this in this	14	deny that this is important.
15	case was the FDA conclusions and not the underlying	15	BY MR. DEAN;
16	documents.	16	Q. Well, your first conclusion your
17	Do you remember that?	17	first basic conclusion, as I understand your summary
18	A. Yes. There is I've not I don't	18	of your report, was that there were it's not clear
19	have a lot I just read 483s and established	19	that there were appropriate pharmacovigilance
20	inspection reports and letters.	20	procedures in place at Actavis Totowa; is that your
21	Q. And so this is no different. This is an	21	a fair summary of one of your primary conclusions?
22	FDA document with a final conclusion and you have no	22	A. The original assessment in the response
23	basis to disagree with it; correct?	23	letter talked about the inadequacies of the
24	A. Not at present.	24	interpretation of the regulations and an
	Q. Okay. Thank you.	25	implementation of the procedures.
25	O. OKAV. I HAHK VOU.		

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# Page 170

Now, let me interrupt you. I'm not talking about what was in the letter. I'm talking about the summary you gave me this morning about the two key points you were --

A. Yes.

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O. -- trying to make in your report.

And one, I think, was the adequacy of the pharmacovigilance procedures and its impact on signal detection and that you were asked to evaluate the system that was in place; correct?

- As much as possible, yes. A.
- Q. And would you agree that this document establishes, at least in the eyes of the FDA as of January of 2007, that appropriate procedures were in place?

MR. THOMPSON: Object to form. I think it mischaracterizes the document.

THE WITNESS: It establishes that appropriate corrective actions were presented to the agency and that the revised procedures were satisfactory.

But it does not establish that there were satisfactory procedures in place during the total period affected.

BY MR. DEAN:

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- Well, your opinion about inappropriate 2 procedures was based upon -- primarily upon the series of 483s and warning letters in regard to pharmacovigilance, wasn't it?
  - Yes. The assessment I made was only on what I was provided in the 483s and Establishment Inspection Reports and responses.
  - And so the primary -- that was the primary basis. And now you see Exhibit 87 for the first time which gives the FDA's final response to that series of observations and warning letters.

And my question to you is --

MR. THOMPSON: Object to the form. 13

14 BY MR. DEAN:

- Q. -- would you like to revise your opinion stated in your report about the adequacy of the procedures at Actavis for pharmacovigilance reporting?
- A. I think that there were definite issues uncovered during the 2006 inspection. There was a shift from 2003, which was NAI, to 2006. And then there was a response letter talking about inappropriate interpretation.

23 I think -- I think the important thing is to look at the actual wording. But the February 24 25 8th, 2006 response talks about problems with

interpretation of the regulations.

And I believe the specifics were in actually assessing 15-day alerts.

I think everything was stamped as a 15-day alert and sent in without assessment of seriousness or expectedness. There were issues documented at the inspection and by the response letters that required the corrective actions.

- Here's my question. It's a very simple question. Would you like to revise your opinion in light of Exhibit 87?
- I can't completely because they required corrective actions, which implies deficiencies, either in the procedures or in the compliance with the procedures.

So there was an issue that required corrective action and required the revision of the procedure.

It's the revised procedures that are satisfactory, not the ones that were revised. Not the baseline.

So I have to be very, very careful and think -- I mean, for me to completely revoke everything looking at one letter and not sitting down and carefully analyzing it is a little dangerous.

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It's as dangerous as making an opinion on inadequate information.

Because this -- the fact that there were corrective actions and procedures that were revised implies that there were problems that required the corrective actions in the revision. The FDA was okay with their plan.

We do not know because we don't have the FDA confirmation of the adequacy of the corrective actions in a future inspection.

If, indeed, this 2008 inspection that had me concerned correlates to this confirmation, then we have some observations consistent with inadequate implementation of this plan that they approved.

So right now, this is very, very important.

- Q. This being 87?
- And potentially would modify it. A.
- Number 87. 19 Q.
- But I still see that it's a -- it's a --20 A.

still a complex and confusing chain of events where a 21 company was on consent decree, they came off, they had 22 apparently clean inspection in 2003, and then things 23 started to happen that required corrective action. 24

Do we know that it was corrected, or was

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### Page 174 Page 176 submitted. 1 it corrected all by transferring to Elizabeth? I 1 I can't tell you based on what I've seen 2 can't answer that at the moment. 2 3 3 if this initial satisfactory answer does not have to Is it fair to say that Exhibit 87 raises be modified based on what happened in 2007 with the 4 significant questions in your mind as to the -- as to 4 5 confirmatory inspection. I'm sorry. 5 your opinion and that you would need more time to 6 You've told us before, if I'm correct, 6 think about the issues and look at the underlying that it's -- you were uncomfortable in your role in 7 7 documents in order to stay and maintain with your 8 this case because you didn't have full information and 8 opinion? 9 that it was -- I think your words were, it was 9 MR. THOMPSON: Object to the form. THE WITNESS: I would like to be able to 10 dangerous to make an opinion based upon inadequate 10 information.Do you agree with that? 11 include all of this new, important evidence in a 11 MR. THOMPSON: Object to the form. revised opinion and revise the white space. Because 12 12 THE WITNESS: I think -- I actually 13 13 there could be more vulnerabilities. think I said that. It may have been a mistake to say 14 And I hope that's not too much of a 14 it. I think part of it is -- I do. 15 hedge. But, yes, this should be incorporated into the 15 -- into the opinion, but with very careful analysis. 16 BY MR. DEAN: 16 You agree that you said that; right? 17 Q. 17 BY MR. DEAN: Now, is it fair to say that as of 18 A. 18 Q. January 3, 2007, the actual MedWatch reports that were 19 And isn't that exactly where we're at 19 here because you're saying that there -- that Exhibit 20 mentioned in the 483 and the warning letter, isn't it 20 21 clear that those had been submitted to the 21 87 raises significant questions, but you have satisfaction of the FDA for this letter? 22 inadequate information to totally evaluate the impact 22 of Exhibit 87? Is that fair? 23 23 This is where I got really --A. 24 A. Yeah, I think --24 Q. Isn't that clear to you? Is that fair? It's not clear based on the totality of 25 O. 25 A. Page 177 Page 175 I think at that point I was provided the evidence. And it might be -- I want to show you 1 1 2 information and I discussed this with counsel. What 2 why, if I can find quickly. I can't search this 3 if they -- I have all of these questions, and I think 3 electronically, but it's back in the 2008. there's information out there that they will present 4 4 I saw their agreement with the FDA for 5 5 the remediation of the lack of compliance with the to me. What happens -- and I asked this at the 6 U.S. Periodic Reports. And that was approved, I 6 7 June 2nd meeting of Megan Carter. What happens if I'm 7 think, actually by Washington. I should clarify that. provided information that is material and requires me 8 8 But there's a statement back here, and I 9 9 to modify my position? think it was the closeout, the minutes of the closeout 10 They said, we'll take it and revise the 10 meeting, where they're going back and talking about position, but we want a preliminary assessment. submitting reports from 2006. 11 11 12 Do you understand that these opinions And I went -- that's when I really got 12 have been filed with the court? 13 13 worried and I do not yet have a clear picture of the Yes. I talked to them about this. 14 A. events from 2006 to 2008. 14 15 Were you concerned about that? Q. 15 Why are they confronting them in 2006 -in 2008 about reports that were to have been submitted 16 A. Yes. I expressed that. 16 And was your concern that you didn't 17 as part of the remediation in 2006, and the company is 17 have enough information on which to base an informed making a statement about not sure how far back they 18 18 19 opinion? Was that your concern? 19 would go. A. I was concerned that I had incomplete 20 20 I have no insight to that. information where I would be vulnerable to being 21 I know that they initially did not want 21 presented with further information that could lead me to remediate anywhere before they acquired, and I 22 22 don't have a lot of insight into the regulatory risk 23 to modify my opinion. 23 And it turns out that that's happened 24 decisions that were being made or why they're saying 24 25 and that you may well want to modify your opinion; is 25 they have to discuss internally what will be

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# Page 178 Page 180 this -- we have to take this and revise the opinion. 1 1 that correct? 2 If I was given advice, please forgive my 2 Possibly. A. 3 3 naivete, but I really made an attempt to deliver a --Okay. Q. an adequate expert witness opinion given the 4 4 But the -- this does not yet explain 5 5 away the 2008 observations and the statements that the circumstances. company employee made about persistent nonreporting of 6 BY MR. DEAN: 6 7 Dr. Frank, isn't it fair to say that you 7 cases in 2006. O. are no longer comfortable in much of the information 8 8 So while it's material, I don't think it 9 can completely negate because --9 in your report? 10 MR. THOMPSON: Object to the form. Q. Let's -- I'm sorry. You go ahead and 10 THE WITNESS: I think it requires 11 11 finish. I want to talk about that in a minute, but I revision based on new evidence. Yes, I'm -- I -- I 12 12 want you to finish. think there's some things, such as the point -- time What is distilled down was 2006, the 13 13 point in 2006 and the time point in 2008, that says 14 14 remediation program, and persistent observations in there were problems with that. 15 2008, and this unexplained comment about submission of 15 cases that apparently were to have been submitted as 16 But I still do not have any real insight 16 into the OSIP, and I only have a few observations in 17 17 part of the 2006 remediation. 2008. 18 So that is still -- and here I'm coming 18 19 And, yes, I think there's a great deal 19 back to this, I asked them -- I told them this 20 -- I think the -- I think that the comments on 20 specifically, I said, this would be the basis of my opinion. And yet, all of this has not been taken into individual observations probably refer well back to 21 21 22 the individual observations. 22 account. Should I proceed with this? But the absolute conclusions probably 23 23 I asked them very seriously what need to be modified based on the evidence that you've 24 24 constitutes adequate documentation for the opinion, 25 how much they can provide for me, how can -- how much 25 provided me. Page 179 Page 181 1 BY MR. DEAN: 1 I can request on any further discovery? And while I recognize -- while 2 2 I asked for a lot of guidance, and I recognizing that the preparation of a report is an trust that they gave it to me appropriately, is in 3 3 4 ongoing process, did you -- were you informed that the 4 taking the information they gave to me, what 5 report that was filed with the Court was supposed to 5 constituted a legitimate opinion before this was 6 be a final report? 6 7 Were you ever told that? 7 This was not done haphazardly. I I was told the deadline and I was told 8 8 actually tried my best to render an opinion based on it would be reviewed. And I asked what I would do in 9 9 what I was granted. this scenario. And I did have some discussion of the But, as we sit here today, you are --10 10 the fact of the matter is, you -- at the time you 11 risk of this occurring. 11 rendered it, you were concerned about inadequate 12 I assumed -- I -- no, I completely 12 anticipated you would do this. 13 13 information. This is why I'm receptive to it, and I'm 14 14 And now, as we sit here today, you have very, very careful to look at it analytically to -- to 15 an even greater concern about inadequate information 15 accept what has to be accepted, but not to be foolish 16 16 being provided to you in order to formulate this and under a state of anxiety back down when I need to 17 17 report; isn't that true? 18 be careful and analytical. MR. THOMPSON: Object to the form. 18 19 I can err in either direction in this 19 THE WITNESS: You've provided me exactly 20 setting and I want to be very, very cautious. 20 what I anticipated might happen and what I raised to Let's go to Page -- go back to Page 5 -the people that hired me and asked me to do this 21 Q. 21 22 A. analysis for them. This is not unexpected. 22 -- in the one, two -- third paragraph. 23 Q. 23 And I asked them how I should handle it 24 A. and the risk and how I should respond to it when it 24 I want to get on to this reference to 25 Q. 25 occurred. And they said, what you do is you take

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### Page 184 Page 182 15 of this document, it says, On May 21, 2008, I Mr. Delicato in 2008 that you've mentioned before and 1 1 issued a Form 483 inspectional observations to try to get into the right set of documents and ask you 2 2 3 Mr. Delicato. 3 some questions on that topic. Okay? So it looks like there was a 483 issued 4 4 That's fine. A. 5 that day, and the Establishment Inspection Report, I Now, I think it's in the second sentence 5 Q. don't know when it was prepared, but, obviously, there 6 6 of that paragraph. was an inspection that day that resulted in the 483 7 It says, In addition, there are 7 and the generation of this -- the EIR. 8 implications of the FDA observation that, quote, 8 9 Would you agree with me there? 9 Mr. Delicato stated that unreported cases from January Yes. And there's also May 20th closeout and February 2006 would be submitted to the FDA. 10 10 However, Mr. Delicato informed me that minutes from which they may have been taken. 11 11 Now, do you know -- well, first of all, 12 they did not have a definitive answer to how far back 12 can we find -- I'd like to find where you're quoting they would go in reviewing unreported cases. He said 13 13 14 Mr. Delicato. they would include this information in their written 14 15 Would that be in a 483 or would that --15 response to the New Jersey District. No. That's why --What -- is that a -- so that's from 16 A. 16 17 Q. That's probably going to be in the EIR, Reference 15; is that right? 17 18 isn't it? 18 And it's in quotations and it's very Or in the May 20th closeout minutes. carefully placed there. 19 19 20 They met with management the day before they issued 20 Hang on. Let me see what 15 is. Okay. the 483. There's -- it's May 20th, 2008. And there So 15 is a May 2000 -- May 21, 2008 FDA 21 21 22 was some background in there, and I think there was inspection report; correct? 22 23 that statement. 23 A. Yes. 24 Can you find -- let's see if you and I All right. So let's get that in front O. 24 Q. 25 can find this statement. 25 of us. Page 185 Page 183 I don't know the background of it, 1 I am handing you, Dr. Frank, what's 1 2 that's why it concerned me. 2 been --MR. THOMPSON: Is it important for us to 3 3 VIDEO OPERATOR: Your microphone. hunt through, or can I point you all on it? 4 MR. DEAN: Sorry. Thank you. 4 MR. DEAN: Yes, if you've got it. No, 5 5 BY MR. DEAN: Dr. Frank, I'm handing you what has 6 show me. 6 7 MR. THOMPSON: It's on Page 8 of 15, previously been marked as Defendant's Exhibit 62. 7 8 right at the end of that long redaction. And the first page of this is a letter 8 9 MR. DEAN: Thank you, Fred. 9 from the FDA to Mr. Delicato, but attached to that is, BY MR. DEAN: 10 10 I believe -- will you agree attached to that is the May 21, 2008 report that you're referencing? Do you see that now? 11 Q. 11 Yes. And it was at the closeout meeting 12 12 Are we talking about the same document? 13 that he stated this. I have no information as to the 13 Yes. May 21, Reference 15. This is --14 background of that. 14 Reference 15, Page 8. Well, Reference 15 in my But there's apparently still unreported 15 15 bibliography is an FDA 483. cases from January, February of 2006, which seemed 16 Oh, I'm sorry. 16 Q. unusual because they did aggregate -- they had -- they No. This may be my error and the fact 17 17 had --18 that I had to redo this bibliography in short order 18 Let me stop you. You're talking about a 19 because we merged the documents. 19 20 closeout meeting -- strike that. I -- well, let's -- this exhibit, we can 20 There was a closeout meeting in regard agree, is the EIR from May 21, 2008 inspection; 21 21 22 to Digitek for Actavis Totowa; correct? 22 correct? 23 There was an inspection in Actavis 23 A. Yes. Totowa from April 21st to May 25th, and I believe it 24 And so you're saying your reference --24 Q. covered more than Digitek. 25 and, in fairness, Dr. Frank, on the top of Page 3 of

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1	Page 186		Page 188
1	I have no way to know whether these	1	Q May 21 inspection of Actavis
2	cases, unreported cases, were Digitek or another	2	Elizabeth.
3	product or the impact on the Digitek case.	3	We can agree on that; correct?
4	There's cases that were supposed to be	4	A. Yes.
5	part of the remediation. Apparently, they're not	5	Q. And you've already told me you don't
6	submitted. I don't know what they are.	6	know whether the events that are being described in
7	I don't know what they are.	7	here are simply related to foreign reporting or not,
1		8	you just don't know one way or another?
8	regulatory risk decision taken by the company. But	9	•
9	this statement am I talking too much?	1	A. Well, the foreign reporting they're
10	Q. No, no. I think we're actually getting	10	talking about the July 2006 and August. This is when
11	to the bottom of this. I think we're going to get	11	Denmark sent them a bulk of cases. Probably most of
12	there in a minute.	12	them should have been in March and April. But I can't
13	So you you don't first of all, on	13	I don't know about the distribution.
14	the quote here on the bottom of Page 8, you don't know	14	But then they're going back and talking
15	whether any of those related to Digitek, we can agree	15	about late cases. And there's the information in
16	on that?	16	here, there may be information in the coding that
17	A. No.	17	tells the case code that tells whether they're a
18	Q. Pardon me?	18	foreign report.
19	A. Very little of the information	19	But I don't know enough about the case
20	Q. Can we agree on that?	20	codes to tell.
21	A. Yes, we agree on that.	21	Q. And all this on Page 8, all this
22	Q. And if you turn the page to Page 9 of	22	really says is that Mr. Delicato said at the closeout
23	15, would you agree that there is, again, reference to	23	meeting of the Actavis Elizabeth inspection that they
24	the Denmark site forwarding reports to the Elizabeth	24	did not have a definitive answer as to how far back
25	site and for processing submission to the FDA?	25	they would go in reviewing unreported cases.
	Page 187		Page 189
1	That's what it says, doesn't it?	1	It wasn't a submission issue, it was a
2	A. This is the bulk submission from 2000,	2	review issue; is that right? Is that the way you read
3	July and August. That was the implementation of the	3	it?
4	March 1st MHRA agreement. Yes, that is what that is.	4	A. Well
5	Q. Do you know one way or another whether	5	O Tales seems times. I want to be foir
6	this exhibit and its observations about AERS, do you	1	O. Take your time. I want to be fair.
		6	Q. Take your time. I want to be fair.  A. There was something else that was left
		I	A. There was something else that was left
7	know whether it is solely focused on foreign adverse	7	A. There was something else that was left outstanding in my mind, and I
	know whether it is solely focused on foreign adverse reaction reporting?	I	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But,
7 8 9	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here?	7 8 9	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment
7 8 9 10	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here?  Q. I'm talking about Exhibit 62. I'm	7 8 9 10	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there
7 8 9 10 11	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here?  Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted	7 8 9 10 11	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in
7 8 9 10 11 12	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here?  Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted to Actavis Elizabeth, LLC.	7 8 9 10 11 12	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in reviewing those cases?
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7 8 9 10 11 12 13 14 15 16	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here?  Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted to Actavis Elizabeth, LLC.  A. No. I do not know whether this is all foreign reporting. I think that  Q. Let me ask you this, then. Are you aware that there was also, I think, an Establishment Inspection Report on Actavis Totowa dated May 20th?	7 8 9 10 11 12 13 14 15 16	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in reviewing those cases?  A. The way he stated it, there were still unreported cases outstanding from January and February 2006. I don't know whether they're foreign. I don't know whether they were cases
7 8 9 10 11 12 13 14 15 16 17	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here?  Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted to Actavis Elizabeth, LLC.  A. No. I do not know whether this is all foreign reporting. I think that  Q. Let me ask you this, then. Are you aware that there was also, I think, an Establishment Inspection Report on Actavis Totowa dated May 20th?  Have you ever seen that?	7 8 9 10 11 12 13 14 15 16 17	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in reviewing those cases?  A. The way he stated it, there were still unreported cases outstanding from January and February 2006. I don't know whether they're foreign. I don't know whether they're U.S.  I don't know whether they were cases that were cited in the inspection report or there's
7 8 9 10 11 12 13 14 15 16 17 18	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here?  Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted to Actavis Elizabeth, LLC.  A. No. I do not know whether this is all foreign reporting. I think that  Q. Let me ask you this, then. Are you aware that there was also, I think, an Establishment Inspection Report on Actavis Totowa dated May 20th?  Have you ever seen that?  A. Yes. I have those two inspections that	7 8 9 10 11 12 13 14 15 16 17 18 19	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in reviewing those cases?  A. The way he stated it, there were still unreported cases outstanding from January and February 2006. I don't know whether they're foreign. I don't know whether they're U.S.  I don't know whether they were cases that were cited in the inspection report or there's no specifics.
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here? Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted to Actavis Elizabeth, LLC. A. No. I do not know whether this is all foreign reporting. I think that Q. Let me ask you this, then. Are you aware that there was also, I think, an Establishment Inspection Report on Actavis Totowa dated May 20th?  Have you ever seen that? A. Yes. I have those two inspections that occurred simultaneously, and I spent a fair amount of time sorting between the two of them. Q. Okay. But the one you quoted from is	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in reviewing those cases?  A. The way he stated it, there were still unreported cases outstanding from January and February 2006. I don't know whether they're foreign. I don't know whether they're U.S.  I don't know whether they were cases that were cited in the inspection report or there's no specifics.  Q. Okay. All right.  A. I can't I can't state that. And I don't know what the how far back means.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here?  Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted to Actavis Elizabeth, LLC.  A. No. I do not know whether this is all foreign reporting. I think that  Q. Let me ask you this, then. Are you aware that there was also, I think, an Establishment Inspection Report on Actavis Totowa dated May 20th?  Have you ever seen that?  A. Yes. I have those two inspections that occurred simultaneously, and I spent a fair amount of time sorting between the two of them.  Q. Okay. But the one you quoted from is the one you quoted from on Page 5 of Mr. Delicato is	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in reviewing those cases?  A. The way he stated it, there were still unreported cases outstanding from January and February 2006. I don't know whether they're foreign. I don't know whether they're U.S.  I don't know whether they were cases that were cited in the inspection report or there's no specifics.  Q. Okay. All right.  A. I can't I can't state that. And I don't know what the how far back means.  I had an outstanding question in my mind
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	know whether it is solely focused on foreign adverse reaction reporting?  A. If you're talking about B here? Q. I'm talking about Exhibit 62. I'm talking about the EIR, dated May 21, 2008, submitted to Actavis Elizabeth, LLC. A. No. I do not know whether this is all foreign reporting. I think that Q. Let me ask you this, then. Are you aware that there was also, I think, an Establishment Inspection Report on Actavis Totowa dated May 20th?  Have you ever seen that? A. Yes. I have those two inspections that occurred simultaneously, and I spent a fair amount of time sorting between the two of them. Q. Okay. But the one you quoted from is	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. There was something else that was left outstanding in my mind, and I Q. First I want to get to that. But, first of all, is it fair to say that this comment reflects that everything had been submitted, but there was just an issue as to how far back they would go in reviewing those cases?  A. The way he stated it, there were still unreported cases outstanding from January and February 2006. I don't know whether they're foreign. I don't know whether they're U.S.  I don't know whether they were cases that were cited in the inspection report or there's no specifics.  Q. Okay. All right.  A. I can't I can't state that. And I don't know what the how far back means.

48 (Pages 186 to 189)

Videotaped

June 30, 2010

Page 190	Page 192
1 before the time of the acquisition, and they were	1 A. I can't tell you whether the
2 attempting to negotiate this with the health	2 implementation of the of the remediation and
3 authorities.	3 there may be there could be blanket statements, and
4 If I did not adequately document that in	4 I'm just not I'm trying to be really accurate here.
I	5 Q. And that's fine.
5 my report, I stand corrected. But there was still	6 A. There could be statements that somebody
6 some question in my mind whether they were making	7 said, yes, it was adequate, but I can't go through
7 calculated regulatory risk decisions.	
8 And that, when he said how far they were	8 here quickly and find them.
9 willing to go back, I can't comment any farther on	9 Q. And my question is, are these I asked
	you whether you were aware of any set of circumstances
	which should have been reported as a MedWatch, which
your many, , more union a management your many	wasn't as of this date, and you referenced the later
1011 15 50)	observations in the 2008 inspection; right?
1 = -	14 A. They're the ones in which I was
	15 concerned about.
	16 Q. If you put those if you put those
as to whether subsequent to that comment what follow-	a a side for the moment because we just talked about
18 up there may have been and what the regulatory	18 those
19 response may have been in regard to that observation;	19 A. Yes.
20 is that fair?	20 Q and you already told us you're not
21 A. I have not seen any subsequent	21 sure whether those are Digitek or not; right?
I I	22 A. Absolutely.
23 into this.	23 Q. So put so we've explored, I think,
24 Q. So that's more missing information;	24 Exhibit 62.
	25 So if you put it aside for the moment,
Page 191	Page 193
1 A. Yes.	1 are you aware of any unreported set of circumstances
2 Q. Okay. Dr. Frank, as of January 3, 2007	2 that would give rise should have given rise to a
3 when Exhibit 87 was issued, are you aware of any	3 MedWatch report in regard to Digitek as of January 3,
4 unreported MedWatch report on Digitek?	4 2007?
5 A. There are inspection observations prior	5 A. No. The only
6 to that, 2007.	6 Q. Was that a
7 Q. Listen to my listen to my question.	7 A. That was a no. The only observations we
8 A. Yes.	8 have are the inspection reports, 2006, and the repeat
	9 inspection. My information does not allow me to track
1	the actions of Actavis in fulfilling the response
2 5 that they had in 2000.	11 letters.
1.2) 4.00.00.10, 0.0 0.10.00.00, 0.,,	12 Q. So you can't testify, as of any point of
12 are you aware of an amoposited trace to appear and	13 time after January 2007, that there was a set of
1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	14 circumstances that should have been in a MedWatch
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
15 there of couple different ways to make part and	
2. West, are you arranged to	appropriate information base to do that, do you?
1. Such a report.	17 A. There were specific cases in 2008 in
The standard of the posterior and the standard and the st	18 this. They were Digoxin. I don't know whether they
	19 were Digitek.
2 o agreements.	20 Q. You don't know?
21 But I don't have any same of	21 A. It's Digoxin, but I think they have some
22 documentation that allows me to track the cases in the	22 sort of XUS Digoxin that I'm not to take into account.
	<del>-</del>
23 inspection observations with the remediation and	23 Q. You are in
2 3 inspection observations with the remediation and 2 4 submissions.	<del>-</del>

49 (Pages 190 to 193)

Videotaped

	Page 194		Page 196
_		1	the press releases to the public, there was a change
1	THE WITNESS: Yes.	2	in risk population.
2	BY MR. DEAN:	3	I brought up the issue that at least in
3	Q. And there's reference on what page to	4	writing informed consents in clinical trials, we write
4	Digoxin?	5	to a fourth- to fifth-grade comprehension level.
5	A. This is Page 9 out of 15, and there's	6	And that when they wrote the press
6	clearly a Digoxin case there.	7	release, there may have been that process to modify
7	Q. Right.	8	the communication. I did not put that in my report.
8	A. But it's not brand Digitek. And I don't have any I didn't get any written documentation	9	But what I did was, I tracked the
9	that I know they have from the from some of the	10	changes in patient population, which did change from
10	•	11	the Health Hazard Assessment to the final
11	other depositions, they have XUS Digoxin, but it's not	12	communication, and the changes in the patient
12	Digitek.	13	population at risk, and I commented on that.
13	And I repeatedly clarified whether XUS	14	I was asked to comment, and I thought
14	cases should be brought into this assessment, and I've	15	there was clearly a change and it clearly changed the
15	been told no. Okay.	16	total patient population that would be warned. And
16	Q. And just for the purposes of time here,	17	that's pretty carefully documented, those changes with
17	you don't know whether this reference on Page 9 of 15,	18	quotes.
18	whether that reference to Digoxin tablets references	19	I did not speculate on why it was done,
19	Digitek or not, do you?	20	on any data that would have supported the removal,
20	A. No. We need to know this case number.  That will code the country of origin of the case.	21	because I had no access to that.
21	, -	22	But they did go from a larger patient
22	So it is possible to tell whether that's	23	population at risk to a smaller patient population at
23	a U.S. case that was just reported as the generic and	24	risk by the time they released the press release.
24	should be taken into account, or whether it's	25	Q. Okay. First of all, would you agree in
25	potentially an XUS case.	<u> </u>	Q. Okty. 1118t of the process of the
l		l	Dago 107
	Page 195		Page 197
1	Q. So, as you sit here today, you're not	1	terms of the recall communication, it was clear to
1 2	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that	. 2	terms of the recall communication, it was clear to everyone that the company wanted the product back and
	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek	2	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?
2	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately	2 3 4	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?  A. Yes.
2	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately reported in a MedWatch; is that correct?	2 3 4 5	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?  A. Yes. Q. Okay.
2 3 4	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately reported in a MedWatch; is that correct?  A. The only thing that I have are these	2 3 4 5 6	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?  A. Yes. Q. Okay. A. A recall is a recall.
2 3 4 5	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately reported in a MedWatch; is that correct?  A. The only thing that I have are these inspection reports.	2 3 4 5 6 7	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?  A. Yes. Q. Okay. A. A recall is a recall. Q. Right.
2 3 4 5 6	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately reported in a MedWatch; is that correct?  A. The only thing that I have are these inspection reports.  Q. Being	2 3 4 5 6 7 8	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?  A. Yes. Q. Okay. A. A recall is a recall. Q. Right. So anyone who, whether they were a
2 3 4 5 6 7 8 9	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately reported in a MedWatch; is that correct?  A. The only thing that I have are these inspection reports.  Q. Being A. And my answer at this point, my	2 3 4 5 6 7 8	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?  A. Yes. Q. Okay. A. A recall is a recall. Q. Right. So anyone who, whether they were a patient, a pharmacist, a doctor, they would have
2 3 4 5 6 7 8 9	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately reported in a MedWatch; is that correct?  A. The only thing that I have are these inspection reports.  Q. Being	2 3 4 5 6 7 8 9	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?  A. Yes. Q. Okay. A. A recall is a recall. Q. Right. So anyone who, whether they were a patient, a pharmacist, a doctor, they would have gotten that message; correct?
2 3 4 5 6 7 8 9 10	Q. So, as you sit here today, you're not aware of any you don't have any specific facts that there was a set of circumstances in regard to Digitek after January 3, 2007, which was not appropriately reported in a MedWatch; is that correct?  A. The only thing that I have are these inspection reports.  Q. Being  A. And my answer at this point, my preliminary answer is, no, I cannot identify it from memory.	2 3 4 5 6 7 8 9 10	terms of the recall communication, it was clear to everyone that the company wanted the product back and off the market and no one should be taking it?  A. Yes. Q. Okay. A. A recall is a recall. Q. Right. So anyone who, whether they were a patient, a pharmacist, a doctor, they would have gotten that message; correct? A. Yes.
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Videotaped

	Page 198		Page 200
1	issued?	1	And that's where I made the question
2	Would you agree with that?	2	that that could be an artifact of the review of
3	A. The FDA inspectors were very, very	3	something being written to a fourth- to fifth-grade
4	concerned about not having received final copies of	4	level.
5	the recall letters.	5	I don't know about press releases to the
		6	general public, whether they have the same
6	Q. Well, my question is, before these letters went out to the various recipients, is it your	7	requirements as the informed consent to clinical
7	understanding and maybe you don't have an	8	trial.
8	understanding, but my question to you is, is it your	9	So we talked about that with the renal
9	• • • •	10	insufficiency. We talked about the removal of the
10	understanding that the FDA would have approved the	11	once daily dosing.
11	substance, not just the substance, would have approved	12	And then I brought up the third change
12	in its entirety the press release, the communication	13	in the in the press release, because the Health
13	to pharmacies, the communication any communication	1	=
14	that was sent out about the recall?	14	Hazard Assessment said lack of efficacy with
15	Is it your understanding the FDA would	15	exacerbation, and that was omitted.
16	have approved that?	16	So there were three changes, daily
17	A. Yes.	17	dosing, renal insufficiency and lack of efficacy were
18	Q. Okay. Now, you	18	distilled down to renal failure.
19	A. I hope that that actually did occur in	19	Yes, you're correct, that could have
20	this case, but I can't perhaps I should have gone	20	been done in negotiations with the FDA. In light
21	back in a very detailed analysis, but I don't think	21	in light of that FDA document that says there was no
22	there is.	22	risk to public health, there may be background to
23	I think there was a concern about the	23	this.
24	delay in the recall procedures and the delay in	24	But there were three changes. And it
25	providing final reports. But, yes, the FDA should	25	does change the direct communication to the patient
***************************************		1	
	Page 199		Page 201
1	Page 199 have approved what was released.	1	Page 201 population at risk.
1 2	have approved what was released.	1 2	
		l	population at risk.
2	have approved what was released.  (Discussion off the record.)  THE WITNESS: It would be in the May	2	population at risk.  Q. Let me hand you what we marked as 37.
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changes.  Q. Now, your point is, if I understand, the point—the basic point in your report is that on this April 25 press release, it mentioned a renal failure, and several days later different communication was conveyed to pharmacies; is that cornect?  A. Well— Q. Is that one of your basic points? A. I have this packet of communications. Q. Right. A. I have this packet of communications. Q. Right. A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that go out to the declorts, the patients, the study coordinators. I do not know whether that is a standard in a drag recall like this. These are two different situations. Q. Right. A. But I don't have any letters directly to patients or directly to doctors. I have only his. January and then there's a press release that went out subsequently. Now, I would have—I the offen key and then there are letters that go out to the declorts, the patients or directly to doctors, it has a standard in a drag recall like this. These are two different situations. Q. Right. A. But I don't have any letters directly to patients or directly to doctors. I have only his. Page 203 and then there's a press release that went out subsequently. Now, I would have—I the first hing in the sequence with the receipt letter. You check the cover letter on the Health Hazard Assessment. Q. We will in a minute. What was the follow-up—there was a follow-up letter that I think our reference in pround the receipt letter hat I think our reference in pround the receipt letter hat I think our reference in pround the receipt letter that I think our reference in pround the receipt letter hat I think our reference in pround the receipt letter hat I think our reference in pround the receipt letter hat I think our reference the manufaction. Q. What's the Bates mumber page there, Dr. Frank? A. It's 28208. But in the April 25 press release, it simply references renal failure. But in the April 25 press release, it simply references renal failure. But in the April 25 press relea		Page 202		Page 204
2 O Now, your point is, if I understand, the this April 25 press release, it mentioned a renal failure, and several days later different communication was conveyed to pharmacies; is that correct?  8 A. Well — C Right.  10 A. I have nothing else. When one stops a colinical trial such as the WHI, there are letters that go out to the doctors, the patients, the study coordinators.  11 Go Right.  12 A. I have nothing else. When one stops a continuous and then there's a press release and the question is why.  10 A. But I don't have any letters directly to patients or directly to doctors. I have only this.  12 Q. Okay.  13 A. But there was granularity omitted from the press release on April 25; right?  14 A. But there was granularity omitted from the press release on the Question is why.  15 Q. Okay.  16 A. But there was granularity omitted from the press release on the question is why.  16 Q. Okay.  17 Q. Okay. So—  18 A. But there was granularity omitted from the press release on her press release was on the 28th. The internal communication to Mylan was on—  18 Q. Exense me. The press—or the news release and the question is why.  19 Q. Right.  10 A. The press release was on the 28th. The internal communication to Mylan was on—  11 A. The press release was on the 28th. The internal communication to Mylan was on—  12 A. Thave call like this. These are two different should be the first thing in the sequence would be the press release on April 25; right?  11 And so when you said A to B to C, A was asked to analyze evidence to support two observations when I was asked to do this.  12 A. Thave saked to analyze evidence to support two observations when I was asked to do this.  13 A. This is the Dear Valued Customer.  14 A. Well, it is more detailed. But it the press release on April 25; right?  15 A. The press release was on the 28th. The internal communication to Mylan was on—  16 A. The press release was on the 28th. The internal communication to Mylan was on—  17 A. This is the Dear Valued Customer.  18 A. A. His the th	1	changes.	1	Q. Right.
A. And then the internal letter went out this April 25 press release, it mentioned a renal failure, and several days later different communication was conveyed to pharmacies; is that correct?  8. A. Well 9. Q. Is that one of your basic points? 10. A. I have this packet of communications. 11. Q. Right. 12. A. I have onlying else. When one stops a clinical trial such as the WHI, there are letters that go out to the doctors, the patients, the study coordinators. 11. I do not know whether that is a standard in a drug recall like this. These are two different situations. 12. Q. Right. 13. Q. Right. 14. A. But I don't have any letters directly to patients or directly to doctors. I have a Health Hazard Assessment, I have communication to Mylan, which never, to my 25 knowledge, reached the public except in this exhibit, 2 Q. Okay. So - 1 and then there's a press release that went out. So I was asked specifically to comment on the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall. 1 Q. Okay. So - 2 A. But there was granularity omitted from the press release and the question is why. 2 Q. Right. 3 A. But there was granularity omitted from the press release and the question is why. 3 Q. Right. 4 And so when you said A to B to C, A would be the first thing in the sequence would be the press release and the question is why. 4 Q. Right. 5 Q. Excuse me. The press - or the news of the press releases on April 25; right? 5 A. The press releases was on the 28th. The internal communication to Mylan was on 10 Q. Excuse me. The press - or the news of the 28th. The internal communication to Mylan was on 18 Q. Excuse me. The press - or the news of the 28th. The internal communication to Mylan was on 19 Q. Excuse me. The press - or the news of the 28th. The internal communication to Mylan with the press release and the open of the risk of the press releases and the open of the press releases and the open of the pre		_	2	· · · · · · · · · · · · · · · · · · ·
4 this April 25 press release, it mentioned a renal failure, and several days later different communication was conveyed to pharmacies; is that correct?  8 A. Well 9 Q. Is that one of your basic points? 9 A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that go out to the doctors, the patients, the study coordinators. 10 A. But I don't have any letters directly to patients or directly to doctors. I have only this. 20 A. But I don't have any letters directly to patients or directly to doctors. I have only this. 21 A. I have a Leath Hazard Assessment, I have a communication to Mylan, which never, to my knowledge, reached the public except in this exhibit, for the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall. 21 A. But there was granularity omitted from the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall. 22 A. They sen selease was on the 28th. The internal communication to Mylan, which never, to my the press release on April 25; right? 23 A. Thave a Realth Hazard Assessment, I A. And so when you said A to B to C, A. Well, it is more detailed. But it more detailed information that was not contained in the press release on April 25; right?  23 A. The press release and the question is why.  24 Q. Okay, So  25 A. The press release and the question is why.  26 Q. Right.  27 A. This is the Dear Valued Customer.  28 A. Well, it is more detailed. But it did.  29 The press release on April 25; right?  20 A. The press release on April 25; right?  21 A. The press release on April 25; right?  22 A. T		·	3	A. And then the internal letter went out
failure, and several days later different communication was conveyed to pharmacies; is that communication.  A. Well —  Q. Is that one of your basic points?  A. I have this packet of communications.  Q. Right.  I A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that go out to the doctors, the patients, the study coordinators.  I do not know whether that is a standard in in a drug recall like this. These are two different situations.  Q. Night.  A. But I don't have any letters directly to patients or directly to doctors. I have only this.  Q. Okay.  A. I have a Health Hazard Assessment, I have a communication to Mylan, which never, to my knowledge, reached the public except in this exhibit. The and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall.  Q. Okay.  Page 203  1 and then there's a press release that went out.  So I was asked specifically to comment on the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall.  Q. Okay.  A. I'm sorry. The Health Hazard Assessment was the 28th. The internal communication to Mylan was on — law your last answer?  A. The press release was on the 28th. The internal communication to Mylan was on — law your last answer?  A. The press release on an the press release. I was the 28th. I have a feeling the press release on the press release on the extent of the press release on the press release. I was the 28th. I have a feeling the press release on the press release			4	subsequently. Now, I would have I don't know about
communication was conveyed to pharmacies; is that correct?  A. A. Well  Q. Is that one of your basic points?  A. I have nothing else. When one stops a clinical trial such as the WFII, there are letters that go out to the doctors, the patients, the study situations.  I do not know whether that is a standard in a drug recall like this. These are two different situations.  Q. Right.  A. But I don't have any letters directly to patients or directly to doctors. I have only this.  Q. Okay.  A. I have a Health Hazard Assessment, I have a communication to Mylan, which never, to my knowledge, reached the public except in this exhibit, and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall.  Q. Okay.  A. Have a Health Hazard Assessment and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall.  A. But Horn was granularity omitted from the press release on April 25; right?  And so when you said A to B to C, A would be the first thing in the sequence would be the press release on April 25; right?  A. The press release was on the 28th. The internal communication to Mylan was on  Q. Excuse me, The press - or the news release was on the 28th. The internal communication to Mylan was on  Q. Excuse me, The press - or the news release that it didn't put in the press release that it did.  This continue that may not contained in the press release.  Condition.  A. Have a Health Hazard Assessment was the 28th. The internal communication to Mylan was on  Q. Expus me, The Pealth Hazard Assessment was the 28th. The internal communication to Mylan was on  Q. Excuse me, The press - or the news release was on the 28th. The internal communication to Mylan was on  Q. Excuse me, The press - or the news release than it did.  A. This is the Dear Valued Customer.  A. The press release was on the 28th. The internal communication to Mylan was on  Q. Excuse me, The press - or the news release than it did.  A. This the p		•	5	- · ·
7 A. Well 9 Q. Is that one of your basic points? 10 A. I have this packet of communications. 11 Q. Right. 12 A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that go out to the doctors, the patients, the study coordinators. 1 I do not know whether that is a standard in a drug recall like this. These are two different situations. 1 Q. Right. 20 A. But I don't have any letters directly to patients or directly to doctors. I have only this. 21 A. I have a Health Hazard Assessment, I have a communication to Mylan, which never, to my knowledge, reached the public except in this exhibit, and then there's a press release that went out. 2 So I was asked specifically to comment on the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect, I agree with you that a recall is a recall. 2 Q. Okay. So 3 A. But there was granularity omitted from the press release and the question is why. 3 A. But there was granularity omitted from the press release and the question is why. 4 Q. Right. 5 A. The press release was on the 28th. The internal communication. 5 One was the sessence of the risk of the press release and the question is why. 5 Q. Right. 6 A. The press release was on the 28th. The internal communication to Mylan was on the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press releases was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the press release was on the 28th. The risk of the p			6	-
8 A. Well — 9 Q. Is that one of your basic points? 1 A. I have this packet of communications. 1 Q. Right. 2 A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that 14 go out to the doctors, the patients, the study coordinators. 16 I do not know whether that is a standard in a drug recall like this. These are two different situations. 19 Q. Right. 20 A. But I don't have any letters directly to patients or directly to doctors. I have only this. 2 patients or directly to doctors. I have only this. 2 have a communication to Mylan, which never, to my 25 knowledge, reached the public except in this exhibit, 2 month there's a press release that went out. 2 So I was asked specifically to comment 3 on the changes from A to B to C, and what the patients 4 and then there's a press release that went out. 2 So I was asked specifically to comment 3 on the changes from A to B to C, and what the patients 4 and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall. 3 the press release and the question is why. 4 And so when you said A to B to C, A would be — the first thing in the sequence would be the press release and the question is why. 4 And so when you said A to B to C, A would be — the first thing in the sequence would be the press release was on the 28th. That's the Dear Valued Customer letter?  A. That's the Bates number page there, Dr. Frank?  A. It's 28208.  Q. So in the April 25 press release, it simply references renal failure.  But in the April 25 press release, it simply references renal failure.  But in the April 25 press release, it simply references renal failure.  But in the April 25 press release, it simply references renal failure.  But in the April 25 press release, it simply references renal failure.  But in the April 25 press release, it simply references renal failure.  A. Yes.  Q. And you believe that's more detailed information that was not contained in the press release — and this is where I was — I was asked t		•	7	Assessment.
9 Q. Is that one of your basic points? 10 A. I have this packet of communications. 11 Q. Right. 12 A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that a go out to the doctors, the patients, the study 15 coordinators. 16 I do not know whether that is a standard in a drug recall like this. These are two different situations. 18 situations. 19 Q. Right. 20 A. But I don't have any letters directly to patients or directly to doctors. I have only this. 21 A. I have a Health Hazard Assessment, I have a communication to Mylan, which never, to my the defect. I agree with you that a recall is a recall. 21 and then there's a press release that went out. 22 So I was asked specifically to comment on the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall. 22 Q. Okay. So 23 A. But there was granularity omitted from the press release and the question is why. 24 And so when you said A to B to C, A would be the first thing in the sequence would be the press release and the question is why. 26 Q. Right. 27 A. That's the 28th. That's an internal communication. 28 Dr. Frank? 29 A. I have a Health Hazard Assessment, I have a communication to Mylan, which never, to my the patients with renal insufficiency; correct? 29 A. But there was granularity omitted from the press release that went out. 29 Co Right. 20 A. But there was granularity omitted from the press release and the question is why. 21 Q. Right. 22 A. That's the 28th. That's an internal communication to Mylan, which never, to my ball that she as the press release, it simply references renal failure. 21 But in the April 28 Dear Valued Customer letter, it talks about patients taking daily doses or patients with renal insufficiency; correct? 23 A. Ves. 24 A. Well, it is more detailed. But it changes the population at risk. So the press release correct? 25 La Well be the first thing in the sequence would be the press relea			8	Q. We will in a minute.
A. I have this packet of communications. Q. Right. A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that 14 go out to the doctors, the patients, the study contained in a drug recall like this. These are two different situations.  10			9	What was the follow-up there was a
11 Q. Right. 12 A. I have nothing else. When one stops a clinical trial such as the WHI, there are letters that go out to the doctors, the patients, the study coordinators. 16 I do not know whether that is a standard in a drug recall like this. These are two different situations. 19 Q. Right. 20 A. But I don't have any letters directly to patients or directly to doctors. I have only this. 22 Q. Okay. 23 A. I have a Health Hazard Assessment, I have a communication to Mylan, which never, to my knowledge, reached the public except in this exhibit. 24 have a communication to Mylan, which never, to my knowledge, reached the public except in this exhibit. 25 and then there's a press release that went out. 25 No I was asked specifically to comment on the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall. 26 Q. Okay. So — 27 A. But there was granularity omitted from the press release and the question is why. 28 The server of the defect. I agree with you said A to B to C, A would be — the first thing in the sequence would be the press release and the question is why. 29 A. Thave a Realth Hazard Assessment to the press release on April 25; right? 29 A. But there was granularity omitted from the press release and the question is why. 30 Q. Right. 31 A. That's the 28th. That's an internal communication. 32 Q. Nath's the Bates number page there, Dr. Frank? 32 A. I have a Continuation. 32 Q. Nath's the Bates number page there, Dr. Frank? 34 A. I have a Hapth Hazard Assessment, I have a communication to Mylan was on patients or directly to doctors. I have only this. 34 A. That is about a communication. 35 Q. Nath's the Bates number page there, Dr. Frank? 36 A. I have a Hapth Hazard Assessment, I have a Hapth Hazard Assessment was the 28th. The releast the patients of the public except in this exhibit. 35 A. That's the 28th. That's an internal communication. 36 Q. Right. 37 Q. Okay. So — 38 Q. Nath's the Bates number pag	ŀ		10	
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25 A. The press release was also on the 25th. 25 put in the April 28 letter; is that correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	and then there's a press release that went out.  So I was asked specifically to comment on the changes from A to B to C, and what the patients and the doctors saw as far as the scope of the risk of the defect. I agree with you that a recall is a recall.  Q. Okay. So  A. But there was granularity omitted from the press release and the question is why.  Q. Right.  And so when you said A to B to C, A would be the first thing in the sequence would be the press release on April 25; right?  And then what is B and C in terms of your last answer?  A. The press release was on the 28th. The internal communication to Mylan was on  Q. Excuse me. The press or the news release  A. I'm sorry. The Health Hazard Assessment was the 28th. Is no, the 18th. The Health Hazard Assessment was the 18th. I think it was sent over on the 25th. The cover letter was the 25th.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	release; correct?  A. Well, it is more detailed. But it changes the population at risk. So the press release and this is where I was I was asked to comment on certain things.  I was asked to analyze evidence to support two observations when I was asked to do this.  One was the systemic issues of pharmacovigilance on signal detection and the other are these changes from one to the next. And that's what I did.  I'll admit, this wasn't sequential.  This actually was a later date than the press release. I will yes, you're correct on that.  Q. Which is which is what date is on that?  A. This is the Dear Valued Customer.  Q. Right.  A. And I questioned what the customer was, and I was told that was internal. That did not go out to the patients, to my knowledge.  Q. And so what you're suggesting is, I think, that the company had information on April 25
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#### Page 208 Page 206 Yes. The internal communications show a 1 (Witness reviews document.) It has 1 2 toxicity -- daily doses or renal insufficiency, and it 2 broader patient population at risk than the contains the lack of efficacy. Yes, I think this one 3 3 communication to the public. 4 tracked verbatim to the Health Hazard Assessment. And you said that while the -- before 4 5 So this, the Dear Valued Customer 5 you mentioned that while the Health Hazard Evaluation letter, tracked the information contained in the 6 report was done on April the 18th, you said it -- I 6 Health Hazard Evaluation report that was transmitted 7 think you said you were right that it was transmitted 7 8 to Actavis on April 25 by Federal Express; correct? 8 on April the 25th; correct? 9 A. Yes. 9 Is that your recollection? 10 Okay. But you didn't -- when you were There should be a cover letter. And, as 10 doing your review, you didn't link that up in your 11 11 I recall, it's the 25th, and I went, why did it take 12 mind, did you? 12 so long to transmit something that was written on the 13 18th? But the April 18th is something I reiterated in 13 A. I think I was operating on the 14 assumption that that press release was made after 14 the document. Well, your memory is actually very good, receipt of the Health Hazard Assessment or 15 15 Q. communication of what was in the Health Hazard 16 16 Doctor. 17 I'm putting in front of you Exhibit Assessment. 17 And that may have been because I made 18 18 220 -assumptions that I -- when I received this assignment, 19 A. Yes. 19 -- which is that cover letter from 20 I was asked to reply on a series. And I did not go 20 Q. Dr. Leikin's group to Sarita Thapar; correct? 21 back. 21 I looked at these dates and I wondered 22 22 Uh-huh. A. why that cover letter was dated the 18th, during --23 And it's dated April the 25th; correct? 23 Q. the 25th and why the Health Hazard Assessment was the 24 24 A. Yes. 18th, but I didn't go back and verify this. I -- and 25 O. And can you -- and for the record, how 25 Page 209 Page 207 1 I don't know. 1 was that letter sent? 2 They may have issued the press release Overnight Federal Express. So it 2 before they got the Health Hazard Assessment based on 3 arrived on the 26th. 3 4 some sort of a preliminary analysis. Perhaps that So it arrived on the 26th; correct? 4 Q. company internal document that I have not seen. 5 5 A. Yes. But from what you have seen and what we 6 6 So on April the 25th, when the press 7 have in front of us, anyway, today, when they issued 7 release was issued, the information in the Health the press release on the 25th, they would not have had 8 Hazard Evaluation had not been received, had it? 8 Unless there was an additional faxed 9 the Health Hazard Evaluation; correct? 9 10 Unless there was a copy faxed in A. 10 copy and this was the follow-up hard copy. followed by the FedEx. 11 And -- but you -- again, that's an area 11 where you don't have information; correct? 12 Q. Okay. 12 13 I actually -- I do not have A. 13 No. And I did not -- I knew that letter documentation of what the supporting documents were 14 14 was the 25th, but I -- I did not connect the fact that 15 the press release went out the day before that would 15 for that press release. 16 The assumption was that the Health 16 have been received if that was the only copy. Hazard Assessment from the 18th would have been 17 And can we also agree that in the Dear 17 wrapped up into external communication for just these 18 Valued Customer letter, the information in here about 18 the two groups, about the daily dosage group and the 19 issues. 19 But that -- that cover letter does beg 20 20 renal insufficiency group, that is contained in the the question because it would have been received one 21 21 Dear Valued Customer letter on the 28th, isn't it? day after the press release. 22 I need to look at this again before I 22 A. 23 At the bottom of Page 6 -- I'm back on answer. Q. 23 24 Exhibit 261, Dr. Frank. 24 Sure. Take your time. It's 28208. Q. 25 The bottom of Page 6 there is a -- the 25 A. 28208.

53 (Pages 206 to 209)

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second sentence says there was a notable absence -- I think you left out the word "of" -- absence of oversight from a centralized headquarters function in Iceland to track local compliance and exchange of information between the U.S. and the EU affiliates.

What is the basis for that opinion?

A. Okay.

Q. First of all, what documentary -- what documents do you have that are even relevant to that issue?

Let's talk about that first.

A. That's why there's an absence.

One of the things the health authorities do in these drug withdrawal cases, for new adverse events, say liver failure or torsade, if the health authority identifies the issue before the company, they go back to the company and say, why are we telling you about a serious safety problem with your drug?

The assumption is that the company should have processes in place to identify the issue first, and then go back and tell the health authority it exists, and then the issue starts into a dialogue of whether this drug has to come off the market.

This is conventional wisdom. And I

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stockpiling reports and sending them in July and August when the implementation date on that MHRA agreement was March 1st.

That could have easily been picked up by tracking those dates, those submission dates.

And so the question comes up, and this is -- this is, again, extrapolating from other cases where the authorities come back and say to the company, why are we telling you about these issues?

- Q. Well, let's stop. First of all, it sounds like you raised with the plaintiffs' lawyers the issue as to whether you had expertise to even comment about this issue; is that fair?
- A. Well, we talked about scope, and I'm talking about systems. And this is on the edge of those systems because I have some experience. I've never done a merger integration.

I was involved with Roche headquarters drug safety reorganization, which was clearly a headquarters reorg. where there was centralization of procedures that had been decentralized, gone out of compliance.

And it's the centralization and headquarters oversight that has frequently been critical in these multinationals that have compliance

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didn't -- I don't want to document the cases where this occurred.

But when I've worked at headquarters, these international companies typically are headquarters holding companies, and each country level affiliate is an independent company under the holding company, and they operate in conjunction with local regulations.

Headquarters typically tracks compliance at the local level. But the responsibility is there.

But there's a growing movement toward tracking this data, spidering this data from local departments onto dashboards of managers.

And so the issue here -- and I talked to them, this is somewhat outside of my expertise, but my question is, I was given no evidence that headquarters identified these noncompliance issues before the FDA 2008 inspection.

So the remediation was to do new processes, to move things to Elizabeth, to make a provision that Copenhagen would send cases to the U.S.

But I have no evidence that headquarters was actually -- had a strong governance function over the individual compliance.

They didn't realize that Copenhagen was

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issues with safety, not just with Roche, but with other companies.

- Q. Did you tell the plaintiffs' counsel in this case this was outside your area of expertise?
- A. I asked if they thought it was and whether I should take it out and they were pleased with that being left in the document.
- Q. But you, yourself, raised the question as to whether it was outside your area of expertise; correct?

That's what I hear you saying. I want to make sure I understand you correctly.

- A. Well, this is my first time as an expert witness, and I'm trying to determine what scope of pharmacovigilance systems is. This is -- this is technically within the scope of --
  - Q. I know. My question was -- I'm sorry.
- A. It may be, but I can't give you a definitive answer.
- Q. My question was very simple. Did you tell the plaintiffs' attorneys this was outside your area of expertise?
  - A. It was possibly.
- Q. Okay. Now, you don't know how Actavis in Iceland was set up structurally to interact with

54 (Pages 210 to 213)

Videotaped

	Page 214		Page 216
1	Actavis in the United States, do you?	1	video record.
2	A. No. We were not given any information	2	The time is 3:30 p.m.
3	as to the headquarters function and overseeing their	3	BY MR. DEAN:
4	affiliates or how much headquarters was initially	4	Q. Do you have any criticisms of the
5	involved with the 2006 inspection, other than to	5	information gathering process for information that
6	ratify the decision at the time of the acquisition to	6	would go into a MedWatch report by Actavis before the
7	implement the MHRA agreement between the two.	7	time of the recall?
8	Q. Is it fair to say you have insufficient	8	A. There are inspection observations from
9	information to be able to comment on the oversight	9	the inspection of January 2006 that there was
10	responsibilities of headquarters in Iceland in regard	10	inadequate information in the cases and inadequate
11	to local pharmacovigilance issues?	11	follow-up, and they cited several cases.
12	A. These may have been placed. I was not	12	So they were looking at the content of
13	given any information to say that there were. And I	13	information, things that were absent, such as
14	don't I don't know I do.	14	concomitant medications and concurrent diseases, as
15	I know that they wanted when they got	15	well as follow-up issues, particularly on a death
16	the first inspection, the initial fix was to move the	16	case.
17	processes to Actavis.	17	Q. Are you aware of any let me reframe
18	There's not a lot of insight into the	18	my question in point of time. Same question, but
19	process of transfer or any other process changes at	19	after January 3, 2007, when the letter that we saw was
20	the time of the acquisition and the merger of some of	20	issued.
21	these acquisition companies.	21	And so after January 3, 2007, are you
22	I guess, there is there's an absence	22	aware of any criticism and before the recall, in
23	of insight into what happened. There's no assurance.	23	that time frame from January '07 to end of April, '08,
24	Q. Do you consider yourself to be an expert	24	are you aware of any criticisms of the information
25	in the issue of recall communications?	25	gathering process by which Actavis gathered
	III the issue of recan communications:		Satisfied by the same of the s
		1	D 017
	Page 215		Page 217
1	A. Honestly, no.	1	information to generate MedWatch reports?
1 2	A. Honestly, no. Q. Okay.	2	information to generate MedWatch reports?  A. No.
1	<ul><li>A. Honestly, no.</li><li>Q. Okay.</li><li>A. I can't say that I've done a huge number</li></ul>	2 3	information to generate MedWatch reports?  A. No.  Q. Okay. Did you ever say to the
2	<ul><li>A. Honestly, no.</li><li>Q. Okay.</li><li>A. I can't say that I've done a huge number of them.</li></ul>	2 3 4	information to generate MedWatch reports?  A. No.  Q. Okay. Did you ever say to the plaintiffs' attorneys in this case that I cannot in
2 3	<ul> <li>A. Honestly, no.</li> <li>Q. Okay.</li> <li>A. I can't say that I've done a huge number of them.</li> <li>Q. Okay. And I think we established before</li> </ul>	2 3 4 5	information to generate MedWatch reports?  A. No. Q. Okay. Did you ever say to the plaintiffs' attorneys in this case that I cannot in good conscience give an expert report in this
2 3 4	<ul> <li>A. Honestly, no.</li> <li>Q. Okay.</li> <li>A. I can't say that I've done a huge number of them.</li> <li>Q. Okay. And I think we established before that what you did in regard to recalls was maybe do</li> </ul>	2 3 4 5 6	information to generate MedWatch reports?  A. No. Q. Okay. Did you ever say to the plaintiffs' attorneys in this case that I cannot in good conscience give an expert report in this litigation because I am concerned that I don't have
2 3 4 5	<ul> <li>A. Honestly, no.</li> <li>Q. Okay.</li> <li>A. I can't say that I've done a huge number of them.</li> <li>Q. Okay. And I think we established before that what you did in regard to recalls was maybe do the Health Hazard Evaluation reports. But you've</li> </ul>	2 3 4 5 6 7	information to generate MedWatch reports?  A. No. Q. Okay. Did you ever say to the plaintiffs' attorneys in this case that I cannot in good conscience give an expert report in this litigation because I am concerned that I don't have all the potentially relevant documents?
2 3 4 5 6 7 8	<ul> <li>A. Honestly, no.</li> <li>Q. Okay.</li> <li>A. I can't say that I've done a huge number of them.</li> <li>Q. Okay. And I think we established before that what you did in regard to recalls was maybe do the Health Hazard Evaluation reports. But you've never participated in drafting the recall documents</li> </ul>	2 3 4 5 6 7 8	information to generate MedWatch reports?  A. No. Q. Okay. Did you ever say to the plaintiffs' attorneys in this case that I cannot in good conscience give an expert report in this litigation because I am concerned that I don't have all the potentially relevant documents?  A. I said I do not think I can render a
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Videotaped

June 30, 2010

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I was asked to rephrase things to say, my opinion based on reasonable evidence, and I did that on June 15th.

So there was a report written that was -- with language where I would be presenting this to a client based on a consulting firm.

And I was given some guidance on how to rephrase the report, and I went in and I rephrased the report where I thought there was FDA inspection observations that would fit together as reasonable evidence, such as I keep repeating, the fact that 2008 still had inspection findings.

It was a question of nonsubmission of cases. There were things like that that became the basis

But I actually trusted them that they were providing me enough information that it was conscionable to form those positions.

They reviewed them and they reviewed the final wording, and I trusted their counsel that this report, although preliminary and possibly requiring revision, was suitable for filing.

Q. Now, did you just tell me that there is a -- I guess it would be on one of these thumb drives -- that there is an initial report that you

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conscience that you might be rendering an opinion without appropriate foundation?

Was that what you meant to convey by your use of the word "conscionable"?

MR. THOMPSON: Object to the form.

THE WITNESS: I'm completely naive to this. I've avoided this for eight years and I was encouraged to write this report based on people who had worked with me who felt that I was qualified to start to take on this kind of work.

I have no way to independently judge my ability to serve as an expert witness. And I don't know whether this is the type of case where you start expert witness.

I trusted the attorneys who provided me with information to give me the information that I needed to determine what was going on.

I went back to them with questions and I did ask about the process of discovery and why there were all these things that I was not provided and would they be provided to me. And I talked to them about what do I do with this information?

And they -- she said -- based on that, I believe that it was okay to render the preliminary report. I did this on advice of counsel and with the

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wrote and then there's a follow-up report that you wrote after you had expressed concerns to the plaintiffs' counsel about what you'd said in your report?

Did I get that correctly?

A. No. I was very, very careful about making too many preliminary comments. I spent an awful lot of time trying to gather and organize the information and track it.

I probably started tracking quality information from manufacturing and trying to assess whether the quality systems were impacting pharmacovigilance. I probably went on a tangent.

But, no, there was no real preliminary report that I revised. I did the report and I was asked to change the wording to the legal wording required for an expert report.

- Q. Now, is the backup to what you just said where you were -- where you made changes in the wording, is that someplace on the thumb drive?
- A. I don't know whether I overwrote it. I think there are early drafts.
- Q. You used the word "conscionable" a few minutes ago.

Were you worried as a matter of your

supervision of counsel.

But knowing that there could be further information that may or may not have been already uncovered with discovery.

And I was told that it is okay to render this preliminary opinion. If they present you with further evidence, you go back and revise it. BY MR. DEAN:

- Q. Is it fair to say that based upon what you've seen today, you are no longer comfortable and you do not stand fully behind this opinion?
- A. I would say yes. My preference would be to, as I was told I could do, incorporate new information.

But -- but, yes, there -- I -- I think that there has to be -- there should be re-analysis of that opinion based on further information. And maybe even some of the information that's not yet presented.

- Q. So is it fair to say that as from your -- with your medical training and your background in the FDA, you, yourself, think that there is an inadequate foundation for your opinion in this report; correct?
- A. I don't have an answer to that. I feel-- Mr. Thompson encouraged me at the break to say,

56 (Pages 218 to 221)

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Videotaped

June 30, 2010

### Page 222

well, you're as much an expert on this as anyone else. I have no way to compare myself to anyone else. I've never even witnessed court proceedings. I deliberately avoided getting involved with litigation. It's not like I've been aiming at

This is something that I was approached about doing a couple times and sort of said, no, no, no, I'm not going to be involved with that.

And I was approached about taking this assignment and very carefully working on it. I asked about the documentation.

And I had to trust the people who had hired me that I was being given correct guidance so that this would be a useful piece of information and a viable one, but I have no way to independently judge that

If -- I should have said, I cannot write this report until I am given all of this, I was given assurance that I'm to render a preliminary opinion based on what was given me.

- So it was your understanding that what was submitted to the Court was just a preliminary report, then; is that right?
  - It was my understanding that these

Page 224

- A. I don't recall. I don't recall whether
- I --

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- Q. Is that the --
- I don't recall whether I pressed him on 4 A. 5 how far I should extend out. I know they've encouraged me several times not to go outside of the 6

7 scope of my assignment in making comments. 8 But that statement was included in the

conclusion with Mr. Miller's approval.

Q. How do you think all this impacts on your credibility, Dr. Frank?

A. I think it demonstrates a very legitimate attempt to do a decent job with suboptimal information. If I did not know to refuse to render an opinion, then I wish I had been informed by the counsel.

But I think it demonstrates my ability to analyze the quality of the evidence and to define things that could potentially be missing. Some of the things that you presented to me I would not have known to even have asked for.

But I raised the issue of whether or not these opinions should be rendered on a series of evidence, and I was given no indication that this was unconscionable or would be seen to jeopardize my

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opinions were to be based on observations that I could 1 2 make based on the present state of the evidence provided to me. I was asked not to say anything 3 4 speculative.

I asked Pete Miller specifically about this comment about the headquarters oversight, and he liked that comment. He did not ask for it to be written.

But I asked, I said, is this -- I don't know -- I can't give you the exact wording, but I wanted to make sure I didn't go out of the scope.

But I was extrapolating these pharmacovigilance systems which usually go into a headquarters oversight.

And he particularly liked that section of the report, and I was given no indication that the inclusion of those statements would be a problem. He approved them.

So I understand that particular Q. exchange, you raised the question about your expertise to give an opinion in that area, and Mr. Miller's response was, I like that opinion. Let's leave it in.

That was the conversation; correct?

- I don't recall the specifics. 24 25
  - O. Is that the --

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credibility.

It may display a learning curve. It may display a naivete at dealing with certain things. But I was never once given any indication that this was unconscionable or unethical behavior.

Even though I questioned, I wanted to make sure that none of this was done, and we discussed it on June 2nd. This is a pretty complex case.

There's a lot of stuff that was not -was not -- I don't know -- I don't know whether it should or should not have been prepared for me, whether it was incumbent upon me to go find the additional information.

I asked for more. Or whether I should have quietly made a determination on the first dossier.

- But we can agree, in your words that you uttered two minutes ago, that the information you had here on which to base your opinion was suboptimal; correct?
- Yes. It was suboptimal. There's --A. there was probably a lot more information out there that was not present.
- And information which might well lead you to change your opinion; correct?

57 (Pages 222 to 225)

Videotaped

1	Page 226		Page 228
	A. Modify the opinion, yes.	1	and I examine what you said give me very carefully
2	MR. DEAN: Let's end this tape.	2	is I realize there's a lot at stake. And I want to be
3	VIDEO OPERATOR: Going off the video	3	careful to do the right thing.
4	record.	4	I was I thought that I was being
5	This is the end of Tape 4.	5	careful enough. And he wants me to stand by what I've
6	The time is 3:46 p.m.	6	written.
7	(A recess was taken from 3:46 p.m. to	7	Q. Were you
8	3:50 p.m.)	8	A. I'm I'm sort of like, this is the
9	VIDEO OPERATOR: We are now back on the	9	first time I've done it, I want to make sure that it's
10	video record.	10	done absolutely correctly.
11	This is the start of Tape 5.	11	And yet, I can tell you right now that I
12	The time is 3:52 p.m.	12	started going through this and going, well, I mean, I
13	BY MR. DEAN:	13	can tell you that there was other information that
14	Q. Dr. Frank, do you realize that there's a	14	would have given indication of the compliance.
15	lot of money at stake in this litigation?	15	But I said, well, they still had
16	A. Yes.	16	inspection findings in 2008. That probably indicates
17	Q. And do you realize there are	17	inadequate implementation of the plans.
18	Court-imposed deadlines for all of us, expert	18	So I've been I've sort of been
19	witnesses and lawyers?	19	encouraged to, even though I may be naive and a little
20	Do you realize that?	20	bit insecure in what I'm doing, stand by this.
21	A. Yes.	21	Now, I just I just don't want to do
22	Q. Were you led to believe that this report	22	anything wrong. I did the best I could with what I
23	that you were going to that you have submitted was	23	was given, and I worked under the guidance of my
24	only a preliminary report?	24	client.
25	Was that the indication that you were	25	Q. Your client being the plaintiffs'
			Page 229
	Page 227	_	
1	given?	1	lawyers; correct?
2	A. I'm afraid so.	2	A. Knowing that you would come with further
3	Not the word "preliminary" was not	3	
1 1		١.	evidence. And how I should respond, he said, well,
4	used, but I was led to believe that there would not be	4	look, you're backing down. You've been shown two
5	any question or problem writing this in this way, and	5	look, you're backing down. You've been shown two additional pieces of evidence. Is that enough to sway
5 6	any question or problem writing this in this way, and that if I was presented with additional evidence, I	5 6	look, you're backing down. You've been shown two additional pieces of evidence. Is that enough to sway your whole opinion?
5 6 7	any question or problem writing this in this way, and that if I was presented with additional evidence, I was to modify this.	5 6 7	look, you're backing down. You've been shown two additional pieces of evidence. Is that enough to sway your whole opinion?  I'm sitting here, well, I guess I'd like
5 6 7 8	any question or problem writing this in this way, and that if I was presented with additional evidence, I was to modify this.  And I Mr. Thompson is concerned that	5 6 7 8	look, you're backing down. You've been shown two additional pieces of evidence. Is that enough to sway your whole opinion?  I'm sitting here, well, I guess I'd like to do another careful analysis. But he's encouraging
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	any question or problem writing this in this way, and that if I was presented with additional evidence, I was to modify this.  And I Mr. Thompson is concerned that I've suddenly backed away from my report because I've been presented with two pieces of evidence.  I'm sorry, maybe I'm just frightened. I don't want to do anything wrong. And maybe I need more assurance than the average person.  But, yes, I did realize there was a deadline. I was a little amazed when I found out that this was actually going to be a big federal case. I thought it was a rather small assignment. But he's concerned that I backed down too quickly.  I don't know how to gauge accurately what is sufficient information to render completely render opinion.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	look, you're backing down. You've been shown two additional pieces of evidence. Is that enough to sway your whole opinion?  I'm sitting here, well, I guess I'd like to do another careful analysis. But he's encouraging me to stand by my opinion.  Q. What I'm interested in is whether you are willing to stand by it given what you have seen today.  And I get the impression that you areyou don't think that there is a sufficient I get the impression you think there's not sufficient information base for you to continue to stand by this opinion.  Am I correct in that impression?  A. I actually don't know how to answer you.  Q. You can't unequivocally stand behind the opinion that you have written, can you?
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	any question or problem writing this in this way, and that if I was presented with additional evidence, I was to modify this.  And I Mr. Thompson is concerned that I've suddenly backed away from my report because I've been presented with two pieces of evidence.  I'm sorry, maybe I'm just frightened. I don't want to do anything wrong. And maybe I need more assurance than the average person.  But, yes, I did realize there was a deadline. I was a little amazed when I found out that this was actually going to be a big federal case. I thought it was a rather small assignment. But he's concerned that I backed down too quickly.  I don't know how to gauge accurately what is sufficient information to render completely render opinion.  I may have I asked many people	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	look, you're backing down. You've been shown two additional pieces of evidence. Is that enough to sway your whole opinion?  I'm sitting here, well, I guess I'd like to do another careful analysis. But he's encouraging me to stand by my opinion.  Q. What I'm interested in is whether you are willing to stand by it given what you have seen today.  And I get the impression that you areyou don't think that there is a sufficient I get the impression you think there's not sufficient information base for you to continue to stand by this opinion.  Am I correct in that impression?  A. I actually don't know how to answer you.  Q. You can't unequivocally stand behind the opinion that you have written, can you?  A. No.

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#### Page 232 Page 230 information about product complaints. Could you tell 1 1 Q. You said that --2 me what -- if you can find it, what page you're 2 I actually was under the impression that A. 3 referencing, Dr. Frank. if I was presented additional information, I was to 3 If you can't find it readily, that's modify the position to accuracy and that there would 4 4 okay, just tell me. But if you can find it, I'd like 5 be no problems whatsoever in taking this course. 5 to look at that page. I realize there's a lot of 6 6 You told me a few minutes ago that there was other information that you had that would have led 7 pages. 7 No, I think it's important because I 8 A. 8 to the conclusion of compliance with appropriate tried to find both. I tried to find as much 9 procedures, but you did not put it in your report. 9 information as I could. Why didn't you put it in your report? 10 10 (Witness reviews document.) I saw it a Can you tell me what I omitted? Can you 11 11 12 while back. 12 give me the specifics of what I said? (Witness reviews document.) 13 I'm just referencing what you said a few 13 Let me do this. Let me see if I minutes ago, that there were -- if necessary, we could 14 14 15 properly understood your reference, and if I did, have the court reporter read your answer back. 15 maybe we don't need to find it. But I believe you said that there were 16 16 I think what you said was there was some -- there's other information that was available that 17 17 information that you picked up and referred to in the would have aided the defendants -- that's not quite 18 18 observations about product complaint information that 19 the way you phrased it -- but there's other 19 20 was appropriately reported. information that would have led to a different 20 21 Is that what you said? conclusion but you left it out of your report. 21 It was an inspection finding that said 22 Do you remember saying that? 22 the remediation for product complaints, there was --23 23 No. I never deliberately omitted any there were no observations with product complaints. opinion -- any evidence that would have swayed the 24 24 And this was probably in 2008. opinion in the direction of the defendants. There was 25 25 Page 233 Page 231 So, then, that would probably be in the 1 no attempt to deliberately omit information. Q. 1 2 2008 EIR someplace? I did not put into the report all of the 2 (Witness reviews document.) Yes. Here. verbal communications, such as the -- all of the 3 A. 3 4 What page are you on, Doctor? I've got Q. Digitek cases would have arisen only in the U.S. 4 5 5 a copy here. Do you --Q. 6 A. 28. But I never specifically said I'm not 6 A. 7 Thank you. going to put this in because it will change the Q. 7 And can you direct me to where you are? 8 opinion in favor of the defendants. 8 Inspection 5, Little Falls, New Jersey, 9 I never would have done something that 9 10 18th of September to October. could have led to that kind of discredibility or lack 10 And I summarized the only thing I found 11 of credibility. There was none of that. And that I 11 in that was the Establishment Inspection Report, under 12 can give you a definitive answer of no. 12 the general discussion, complaints were reviewed, 13 If I forgot to put something in, it was 13 14 there were no deficiencies found. an error or I did not realize that I was to put in 14 I have no ability to assess the impact 15 15 verbal information. of the sampling of the complaints in this inspection I did put information in of inspection 16 16 and the direct impact on Digitek. findings of compliance with product complaints. I had 17 17 There was a supplemental document that the interim information for product complaints that 18 18 showed -- and there was -- there's a comment from the 19 19 you showed me for safety. FDA in here, that the compliance with 30-day timeline 20 But it was actually an inspection 20 for product complaints improved over the course of confirmation, and that's in here. And I put it in 21 21 2007 to the point of the inspection. 22 because I thought this would be one report with some 22 And we have talked before about the fact 23 -- the conclusions to support. But I did not 23 that one thing you would like to see is the product --24 deliberately omit any information. 24 in the course of investigating a product defect, would 25 Could you tell me -- you just referenced 25

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#### Page 236 Page 234 your report, having, you know, engaged in the dialogue 1 be good communication between the product complaint 1 2 side and the signal detection side. 2 with me today, do you feel that you have been misled 3 3 by the plaintiffs' lawyers regarding the factual basis Do you recall that discussion? 4 4 A. Yes. for your opinions? I don't know how to comment on that. I 5 And so what you're saying, I think, is 5 A. 6 that, at least from this observation on Page 28, that 6 thought that I got a dossier that was not in 7 7 chronological order. as of 2006, the product complaint side appeared to be 8 functioning appropriately; correct? 8 I wasn't sure that I got the full 9 9 component of the documents. I wasn't sure that the Is that the appropriate -full components had actually been discovered on part 10 I don't know what the scope of that is. 10 11 Complaints review. Did they just look at the 11 of discovery. 12 12 complaint files? I cannot say I was deliberately misled, 13 13 particularly because -- I don't know how to answer I spent some time trying to assess 14 whether every complaint had an accompanying Health 14 15 15 I had to assume that if they wanted me Hazard Assessment. 16 And what I ended up putting weight on 16 to write an expert report to be filed in this case was the FDA observation, because they had access to 17 17 that they would take a lot of care to provide the best 18 the information in 2008. They were concerned about 18 documentation possible. 19 I can't rule out bias, but I'm -- I have 19 the lack of ongoing Health Hazard Assessments. 20 And in order to get through all of the, 20 to say that that's not my point to assess. Perhaps I 21 I want to say, lack of evidence and confusion, because 21 should not have made an assessment about the 22 discovery, but I was surprised by the sampling of the 22 I couldn't completely sort that out. 23 And I spoke to them about this, that to 23 evidence. 24 base my opinion on the FDA inspector who looked at the 24 I thought I would get everything so I'd be able to track things out. That may be my 25 primary evidence, even though I did not have the 25 Page 237 Page 235 1 misunderstanding on what is adequate evidence. 1 access to it. 2 2 Q. Are you --So that's where I can't come -- I can't 3 3 And my -- is it my inability to render reconcile that with the FDA inspector's concern in opinion on what is adequate evidence that is the core 4 4 2008 that there were no accompanying Health Hazard 5 Assessments. 5 of the problem? Or do I rely on the people who 6 I don't know what the overlap was, 6 provide it to me to ensure that this is adequate for 7 7 whether they were fine here and then there were a the opinion that I render? 8 8 But you would agree that this is a problem. I can't tell you that. 9 And this is another manifestation of the 9 troubling issue given the lack of information that you Q. 10 fact that you were not provided the underlying 10 had? 11 I think it's a -- yeah, I think it's --11 documents; correct? A. 12 A. I would assume so, yes. 12 I think that -- yes, it does bother me. 13 13 And at the end of the day, having, Q. Okay. again, looked at all the documents, engaged in all the 14 14 A. Or I wasn't given any other Health 15 15 dialogue that we have, are you still willing to Hazard Assessment other than the one from Dr. Leikin. 16 I had no documentation of any Health Hazard Assessment 16 continue to serve as an expert witness on behalf of 17 in 2004. I asked for it. And I looked for them. 17 the plaintiffs in this litigation? My number one concern in this situation 18 And I had -- the FDA -- the thing that 18 19 is that I don't do anything considered wrong or I 19 became the basis of the opinion was that inspector --20 FDA inspector in 2008 and their concern with the 20 don't have problems with the fact that I'm new to this 21 21 and I will have to learn certain things. absence of them. 22 22 Having heard everything you've heard But I don't want to do anything that 23 would be considered incorrect. 23 today in the sense of being shown documents, 24 additional documents today, having gone over all the 24 Now, I agreed to do this. I 25 25 communicated my concerns. There's an interest for the documents we have in front of us, having gone over

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1	plaintiff in my standing by my opinions.	1	Q. So to the extent you've now learned
2	I have little or no interest in going	2	that; correct?
3	into a public deposition before a panel of judges and	3	A. Yes.
4	finding that I have to I don't I don't want	4	Q. Correct?
5	to destroy myself.	5	So to that extent, you were misled;
6	I asked if I was you know, if I was	6	correct?
7	considered too lightweight a witness to hold up this	7	A. The
8	case. I have no way to independently judge that.	- 8	MR. THOMPSON: Object to the form.
9	But it's extremely important that my	9	THE WITNESS: The preliminary
10	level of expertise is sufficient to hold the weight.	10	communication from the consulting firm is they had
11	Even if this is an opinion that doesn't support	11	received a request for somebody to do an expert
12	eventually.	12	witness on pharmacovigilance systems.
13	But I have no I have no way to	13	And I asked what that would entail. And
14	independently judge whether I am truly an expert	14	they said, you'll be sent evidence and you try to come
15	witness. What does that constitute?	15	up with a truthful answer. And you'll have to sit
16	Is it a few people saying you are, we	16	deposition. But
17	want you to do this? We've done it. There may be	17	BY MR. DEAN:
18	another expert witness who's asked to critique your	18	Q. Excuse me. Mr. Thompson actually gave a
19	work.	19	good objection there because let me rephrase that
20	But I've not been led to believe that,	20	question.
21	given my present abilities or knowledge, that pursuing	21	Do you feel you were misled by Smart
22	this is foolish, unethical. I can't say that I've	22	Consulting about what your role was going to be in
23	been led to believe that.	23	this litigation?
24	And yet, it's my strength of ego to say	24	A. I was led to the what I agreed to
25	to you, yes, I will stand by this and I will argue and	25	do would have stopped at the end of today.
	Page 239		Page 241
1	argue.	1	I did not agree to sit expert witness
2	And yet, I have doubts about I can't	2	before a panel of federal judges, and then I found out
3	say I've done this five times successfully and,	3	even later that Pete Miller wanted me to be a witness
4	therefore, I've demonstrated my ability. I can say	4	in the actual litigation in November.
5	that I've been encouraged to pursue this and to submit	5	These things were sequentially disclosed
6	this document.	6	to me, and my level of comfort with my own
7	And I've made certain, as I'm doing	7	inexperience and not knowing how to gauge my preparedness was real.
8	this, by asking for external confirmation that I've	8	Q. Is it fair to say that you would have
9	not been doing anything foolish or incorrect.  Q. Knowing that there is a lot of money at	10	declined this assignment if you had been told at the
11	Q. Knowing that there is a lot of money at stake, knowing that there are court rules in place for	11	beginning that you would have to testify in court
12	expert reports, knowing that expert reports have to	12	before a jury?
13	have appropriate foundations, my question to you is,	13	A. I never really wanted to get into this
14	are you willing to continue as an expert witness in	14	line of work. I was led to believe this was a very
15	this case?	15	limited assessment. I was not aware at the outset
16	A. The honest answer is, I never wanted to	16	that it was a bunch of state litigation that had been
1		۱.,	rolled up into a federal case.
17		17	Toned up line a rederar case.
17 18	have to sit expert witness in court. That was not	17 18	There was there was no up-front
l l		l	
18	have to sit expert witness in court. That was not disclosed to me at the time I agreed to do this. I	18	There was there was no up-front
18 19	have to sit expert witness in court. That was not disclosed to me at the time I agreed to do this. I agreed to write a report and sit deposition on the	18 19	There was there was no up-front communication of the extent of the work or the high-profile nature of the case or and I had no assessment of my potential impact on the outcome.
18 19 20	have to sit expert witness in court. That was not disclosed to me at the time I agreed to do this. I agreed to write a report and sit deposition on the report that I made, on the evidence I was given.  Q. Are you telling me that you weren't told that you might have to testify in court? Is that what	18 19 20 21 22	There was there was no up-front communication of the extent of the work or the high-profile nature of the case or and I had no assessment of my potential impact on the outcome.  I don't know whether I'm a small fish or
18 19 20 21 22 23	have to sit expert witness in court. That was not disclosed to me at the time I agreed to do this. I agreed to write a report and sit deposition on the report that I made, on the evidence I was given.  Q. Are you telling me that you weren't told that you might have to testify in court? Is that what you're telling me?	18 19 20 21 22 23	There was there was no up-front communication of the extent of the work or the high-profile nature of the case or and I had no assessment of my potential impact on the outcome.  I don't know whether I'm a small fish or a big fish in the outcome. I can't say that.
18 19 20 21 22	have to sit expert witness in court. That was not disclosed to me at the time I agreed to do this. I agreed to write a report and sit deposition on the report that I made, on the evidence I was given.  Q. Are you telling me that you weren't told that you might have to testify in court? Is that what	18 19 20 21 22	There was there was no up-front communication of the extent of the work or the high-profile nature of the case or and I had no assessment of my potential impact on the outcome.  I don't know whether I'm a small fish or

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	Page 242		Page 244
l 1 te	estifying witness in court?	1	litigation is. And I understand no, I understand
2	You were not told that; correct?	2	I understand what this is.
3	A. No.	3	I just wish I had this may be a self-
4	Q. You were no, you were not told that;	4	confidence issue with me. I don't know how to gauge
5 c	orrect?	5	my preparedness. I may be completely prepared. I may
6	A. No, that was not disclosed at the	6	be very good at this, but I can't tell you whether I
7 o	utset. There was sort of a sequential disclosure of	7	am or I'm not.
8 in	ncreasing levels of involvement.	8	Q. But you do wish that it had been
9	Q. When was it that you were finally told	9	disclosed to you much earlier that you were expected
10 th	hat you would be asked to testify in court before a	10	to testify in front of a court or jury; correct?
11 ju	ury?	11	A. Yes. I would have preferred my first
12	A. I don't know the exact date, but I	12	expert witness assignment to be limited in scope so
l	elieve sort of about the time I had lunch with Pete	13	that there was an assurance of the accuracy and the
1	Miller. It may have been a phone call, it may be at	14	success.
15 th	he June 2nd lunch.	15	That the magnitude of this case and that
16	But and I didn't know whether he was	16	the questions that I raised about the discovery and
	naking this assessment to bring me further in the case	17	what was being sent to me had not arisen. You know,
1	ased on his preliminary interactions, whether this	18	maybe I'm out of line as an expert witness saying what
19 w	vas a change in plans, or whether or how this all	19	about the discovery?
20 o	ccurred.	20	I assumed that all of these blank
21	I can't judge I really I don't	21	documents, these white spaces, would be sent to me.
	vant to judge his motive. I just know there was a	22	When they told me that they weren't sure
	equential expansion of this.	23	they already had them and they may be able to obtain
24	Q. When you I said before you	24	them, because there may be one more round of
25 m	nentioned that I think you were drafting a report on	25	discovery, I just went be as technically, if I'm
	Page 243		Page 245
1 Jı	une 15th.	1	I thought I should have everything to track through
2	As you were drafting on June 15th or	2	the period and maybe track from the consent decree.
3 th	hereabouts, at the point where you were writing this	3	But I don't I can't tell you I'm
4 10	ong report, did you understand you were going to have	4	right or wrong based on experience.
5 <b>t</b> c	o testify in court?	5	Q. Dr. Frank, is it fair to say that you
6	A. Possibly, yes. Yes. Yes.	6	have significant misgivings about your ability to
7	Q. Possibly or for sure?	7	qualify as an expert witness and you have significant
8	A. I I was told that, in all likelihood,	8	misgivings about the quality of the information that
9 I	would be asked to present at the science day.	9	supports the opinion that you have written here?
10	Q. At the science day?	10	Would that be fair to say?
11	A. Which is October.	11	A. I hate to say significant misgivings
12	Q. Were you ever told that you would be	12	because I've been assured that I've been given
	ave you ever been told that you would be asked to	13	assurance that moving forward with doing this I would
	estify in one of the individual actions?	14	not have embarrassment or problems.
15	And by that I mean a case in which one	15	Q. And who has assured you that you would
	of the plaintiffs is suing the defendants to try to	16	not have embarrassment in the future as we move
l .	btain a money judgment against the defendants.	17	forward in this litigation?
18	Have you ever been told that you would	18	A. The people at Smart Consulting, Nigel
	be expected to testify in one of those cases?	19	Smart and Denise Smart.
20	A. I was told that they may ask me to	20	Q. And what did he tell you? Tell me what
	appear in November, in a November case. In all	21	assurance how did he articulate this assurance that
	ikelihood, I would be.	22	you would not be embarrassed as we moved forward?
23	And oh, no, I do understand	23	A. Well, he said, really all you have to do
	iability. No. I understand the magnitude of this.	24	is try to get to truth. We're just seeking that. And
25 I	understand what rolling up a bunch of state-level	25	on the evidence presented to you, you try to sort out

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	Page 246		Page 248
1	what truth is.	1	And I looked at it, and I said to
2	And I got to a situation where I was	2	myself, I hope that in rewording these statements I
	like, I became concerned that I hadn't been I	3	actually have am making it on what is considered
4	didn't have all of the communications.	4	reasonable evidence.
5	I didn't have I didn't have anything	5	That I was provided the reasonable
6	to confirm I just got the FDA I was asked to	6	evidence and I can trust that, and that I was able
7	make the determination only on the FDA inspections and	7	this is I was provided huge amounts of documents
8	some letters. The letters say we're going to do this.	8	about manufacturing and analytical issues.
1	I don't have the details of what was	9	But there was a question in my mind
9		10	about what was reasonable evidence in this case? Do I
10	done or the tracking that showed that it was done.	11	have to go through every CAPA tracker?
11	And this is stuff that typically is	12	And I do want to make sure before this
12	given to consultants when they go in and assess		is actually admitted that I don't want to let my
13	vulnerabilities to repeat inspections. And I asked	13	•
14	about it.	14	insecurities, which could just be me I might have
15	Q. So is it fair is what you're saying,	15	simply done an analytical analysis.
16	there might be a basis for the opinions you've given,	16	But, yes, I these opinions were
17	but you're not sure because you haven't seen the	17	there. I can't see that a lot of things that would
18	evidence? Is that what you're saying?	18	typically have been done have been done.
19	Isn't that a fair summary?	19	I was asked I was asked to support
20	A. Yes. I can assure you that I did the	20	certain opinions that counsel wanted supported. And
21	best that I could with what I was given. And I based	21	so what I did was took the evidence and I couldn't see
22	it heavily on a few FDA observations from point to	22	anything to the contrary.
23	point. But there's interim space where I don't have a	23	If I had had a clean inspection in 2008,
24	lot of insight into what went on.	24	I would have said, the evidence for adequate
25	It's the FDA inspection, the	25	remediation is the inspection from 2008. Now, he
	Page 247		Page 249
	· ·		
1		1	,
1 2	communications, and the confirmatory inspections.	1 2	subdivided the inspection.  Did you see evidence in 2008 that they
2	communications, and the confirmatory inspections.  MR. DEAN: Thank you.	i	subdivided the inspection.  Did you see evidence in 2008 that they did not remediate the quality of the reports? So the
2 3	communications, and the confirmatory inspections.  MR. DEAN: Thank you.  Give me just a minute, Fred.	2.	subdivided the inspection.  Did you see evidence in 2008 that they did not remediate the quality of the reports? So the
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Videotaped

Q. And you have expressed all of those opinions in Exhibit 261; right?  A. The answer to that is, I cannot tell you because I thought these two were going to go together. Q. Okay. This is your report, Exhibit 261; right?  A. This was split off. This up until maybe it was mid-aftermon, I have to look, on the 15th, I thought I was submitting all of this together. So that there was a much careful tracking between the observations and my comments.  So my concern is that since this was split off. The was a firm of the term of the ter		Page 250		Page 252
opinions in Exhibit 261; right? A. The surver to that is, I cannot tell you because I thought these two were going to go together. O. Okay. This is your report, Exhibit 261; right? A. This was split off. This up until maybe it was mid-afternoon, I'd have to look, on the 15th, I thought I was submitting all of this together. So that there was a much careful tracking between the observations and my comments. Do my concern is that since this was hundred percent transfer of every single opinion in here to here. There was just sort of a high-level overview.  Q. And what we have been presented is the report of Karen A. Frank, M.D., dated June 15, 2010, as contained in Exhibit 261, which you have entitled Background, Analysis and Conclusions; correct? A. Yes. It was segments - Q. And Section 3 is called Analysis and Conclusions; right?  Page 251  in Section 3 of Exhibit 261? A. Yes. Q. Okay. And what I'm wondering as I listen to you talk today about evidence that wasn't given to you before you prepared this report by plaintiffs' counsel, and that you have only learned about is not lead at you have only learned about is not lead at you have only learned about is not lead at you have only learned about is not lead at you have only learned about is not lead at you to you prepared this report by plaintiffs' counsel, and that you have only learned about is not you talk today about evidence that wen't flaw, raise your right hand and be sworn to tell the truth and to stand by with confidence the opinions that you have expressed in Exhibit 261?  M. Mr. THOMPSON: Object to the form.  The WITINESS: If prefer to have substantially more evidence before I had to do that.  Share to provided.  A. Yes. Considered reasonable evidence.  You're being paid for your services; right? A. Yes. Q. You have rendered those opinions; right? A. Yes. Q. You have rendered those opinions; right? A. Yes. Q. And that's sur opportunity to determine whether or not there is a ranging for bour intention to the stand and to the the value of the value of th	1		1	
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Videotaped

June 30, 2010

	Page 254		Page 256
1	and say to these judges under oath that you express	1	yourself.
2	the opinions that are contained in Exhibit 261 to a	2	A. Yeah.
3	reasonable degree of scientific probability that these	3	Q. And what I want to know is, whether
	are correct and that you, as a medical doctor, who has	4	you're willing to stand behind these opinions and go
4	worked for various pharmaceutical companies and for	5	into a court of law and to say with confidence, the
5	the FDA, can say with confidence that you stand behind	6	opinions you've given here today, that you stand by
6	· · · · · · · · · · · · · · · · · · ·	7	these opinions, as a person of integrity?
7	those opinions.	8	A. You have both led me to believe that
8	Are you willing to do that?		there's additional evidence that I was not presented,
9	MR. THOMPSON: Object to the form.	9	
10	THE WITNESS: Should I discuss this with	10	even though I asked for it. And proceeding forward, I
11	you?	11	could face significant embarrassment, if not
12	MR. KAPLAN: No. Just answer my	12	questioning, of the opinions.
13	question.	13	And the whole time I did this, I tried
14	MR. THOMPSON: I think that the question	14	to document very, very carefully. And yet, you're
15	is on the floor.	15	leading me to believe that this is a great
16	THE WITNESS: I really don't want to,	16	embarrassment and that I've done an inadequate job and
17	but I'm concerned about the fact that it's just that I	17	I can't support what I've done.
18	only wanted to do the preliminary background work, the	18	He doesn't think I should back down.
19	supportive work, and end with a private deposition	19	And the only thing I can think of is I don't want to
20	like this.	20	do anything wrong.
21	When they told me I had to go to court,	21	Q. What do you think you should do?
22	I was like, this is a huge issue. I'm completely	22	A. I would like to if I could, I would
23	naive with this, and I don't know how to judge my	23	like to stop with only doing background supportive
24	preparedness.	24	work.
25	And I most certainly the most	25	Q. Well, let me say that that's not the
	Page 255		Page 257
1 .	important thing is, I don't want to do anything that	1	option right now.
2	would be considered wrong.	2	A. It's one or the other?
3	If I've gotten into something where the	3	Q. Yes. Either you go forward or you back
4	work product is inadequate, he's concerned that I'm	4	down.
5	backing down based on the presentation of two or three	5	A. What if I choose not to go forward?
6	pieces of evidence. And I'm at a loss to know the	6	What are the implications?
7	right course of action.	7	Q. That's up to you. You can say, I
8	I'd prefer not to testify in a high-	8	withdraw as an expert here. I'm not comfortable with
1	profile case. If I do, I'd like to make certain that	9	it.
9	I'm presented everything. I was actually led to	10	A. But what are the implications of that?
10	believe that if you presented me with more evidence	11	Will I be in a lot of trouble?
11		12	Q. You won't be in trouble. You just won't
12	today, this would be revised.	13	be an expert in this litigation.
13	And I'm concerned about that, because	14	MR. THOMPSON: Well, I am going to
14	that would allow me to go through this if they found	15	object and I am going to say that this would be
15	more information and make sure everything was correct.	t .	something that I would view as something that would
16	BY MR. KAPLAN:	16	I would be entitled to confer with the expert witness
17	Q. This is it. This is our opportunity to	17	
18	examine you on the report that you have given	18	about is that question about withdrawal.
19	A. I know.	19	THE WITNESS: Okay.
20	Q in the Multi-District Litigation	20	MR. THOMPSON: Certainly you can
21	that's pending in Charleston, West Virginia, and in	21	question her about the report. You can question her
22	the Pennsylvania consolidated litigation, which is	22	about the documents. You can question her about all
23	pending here in Philadelphia.	23	that.
24	There are about a thousand cases that	24	But I believe that I would have an
25	are riding on opinions of expert witnesses here like	25	opportunity to confer with her about that issue of

65 (Pages 254 to 257)

	Page 258		Page 260
1	whether she would continue employment or not.	1	But at this point, I didn't know that
2	BY MR. KAPLAN:	2	this was such a heavy assignment when I agreed to do
3	Q. What do you want to do?	3	it, and I didn't feel that I should withdraw when they
4	A. The right thing.	4	told me this when they felt I was strong enough.
5	Q. What do you think that is?	5	But now I'm being seriously questioned,
6	A. The safe thing is to withdraw. If at	6	and I would have preferred to have this be a limited
7	this point I can withdraw and there will be no	7	assignment and to not jump right into a very big case.
8	questions that I've done the best I could and there's	8	As you said, there's very, very high
9	tremendous there may be more risk to everyone if I	9	risks. There's no way I can assess the real risk.
10	proceed.	10	And all that I can think in my head right now is I
11	You're basically saying that if at this	11	just don't want to do the wrong thing.
12	point there's question that putting me on a witness	12	And that's what I did for two to three
13	stand can be an embarrassment or jeopardize the	13	weeks when I took this assignment.
14	litigation, then the right thing to do would be to	14	I just don't want to get into anything
15	withdraw.	15	that's wrong, that I can't do appropriately. That's
16	But I hope I could do that without being	16	my only concern.
17	accused of doing anything wrong. I would hope that	17	Q. Well, my concern and Mr. Dean's concern
18	people would say she did the best she could with what	18	is that our clients are being accused of wrongdoing.
19	she was given and under the guidance she was given.	19	A. I'm not trying to do that.
20	But I have been so frightened when I	20	Q. And our clients are being accused of
21	say frightened, since I started this, that I would do	21	selling and distributing
22	something wrong and there would be consequences, that	22	A. Oh, your clients. Oh, I'm sorry.
23	this could just be my fear because I'm naive to this.	23	Q defectively manufactured Digitek.
24	I've stayed away from it even though	24	A. I was thinking the law firm. I trusted
25	people have encouraged me to get into it.	25	their counsel. I thought you were asking me no, I
·····		[*************************************	
ļ	Page 259		Page 261
1	Page 259  And Liust Ldon't want to do	1	•
1 2	And I just I don't want to do	1 2	take that initial response back.
2	And I just I don't want to do anything wrong where there would be consequences for	2	take that initial response back.  Q. I want you to understand this is very
2 3	And I just I don't want to do anything wrong where there would be consequences for me, even to question my credibility. That's my number	.3	take that initial response back.  Q. I want you to understand this is very serious business.
2 3 4	And I just I don't want to do anything wrong where there would be consequences for me, even to question my credibility. That's my number one concern.	2 .3 4	take that initial response back.  Q. I want you to understand this is very serious business.  A. It's very serious.
2 3 4 5	And I just I don't want to do anything wrong where there would be consequences for me, even to question my credibility. That's my number one concern.  And I may have to say that I did	2 .3 4 5	take that initial response back.  Q. I want you to understand this is very serious business.  A. It's very serious.  Q. Millions of dollars are being sought
2 3 4 5 6	And I just I don't want to do anything wrong where there would be consequences for me, even to question my credibility. That's my number one concern.  And I may have to say that I did something I was told I keep being told to have	2 .3 4 5 6	take that initial response back.  Q. I want you to understand this is very serious business.  A. It's very serious.  Q. Millions of dollars are being sought from our clients.
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	Page 262		Page 264
1	I told you this. I don't know how much	1	at the FDA, and who places great reliance on the
2	this all supports directly the Digitek case.	2	integrity of the FDA
3	I never saw information that subset the	3	A. Yes.
4	direct impact on Digitek. I can only make	4	Q you do that, don't you?
5	generalization statements. And I hope they aren't	5	A. Yes.
6	wrong generalizations. There is more evidence to be	6	Q. And you have testified that in the
7	obtained.	7	opinions you've rendered, you relied upon FDA
8	Q. And you certainly never saw any evidence	8	inspection reports
9	that any person received defectively manufactured	9	A. Yes.
10	Digitek, did you?	10	Q and what the FDA inspectors have
11	A. No.	11	said?
12	MR. THOMPSON: Objection. Asked and	12	A. Yes. Solely. I am relying on their
13	answered.	13	assessment of the primary data.
14	BY MR. KAPLAN:	14	Q. And so, after all is said and done,
15	Q. Did you?	15	after all of these inspections and after all of your
16	A. Well, I was told this would be asked.	16	reliance on what the FDA inspectors have said with
17	Now, what I know is that there were an influx of cases	17	regard to the primary data and after the recall, we
18	after the recall was announced. I have not been given	18	come full circle, do we not, to Plaintiffs' Exhibit
19	any of that evidence. That was sent to someone else.	19	38, which you were shown today?
20	Q. So what I'm saying to you is	20	A. Yeah.
21	A. I haven't.	21	Q. Right?
22	Q you've never seen any evidence	22	A. Uh-huh. Yes.
23	A. No.	23	Q. Okay. And that's entitled Facts and
24	Q to support an allegation that any	24	Myths About Generic Drugs; right?
25	consumer ever ingested defectively manufactured	25	A. Yes.
23			Page 265
	Page 263	1	rage 203
1	Digitek, have you?	1	Q. And that's a statement of the FDA;
2	Digitek, have you?  A. No, I've not been provided that. I've	2	Q. And that's a statement of the FDA; right? Correct?
2	Digitek, have you?  A. No, I've not been provided that. I've been provided evidence evidence that says that it's	2 .3	Q. And that's a statement of the FDA; right? Correct? A. Yes.
2 3 4	Digitek, have you?  A. No, I've not been provided that. I've been provided evidence evidence that says that it's worth being investigated further. But I've not really	2 3 4	<ul> <li>Q. And that's a statement of the FDA;</li> <li>right? Correct?</li> <li>A. Yes.</li> <li>Q. And it's a very important statement of</li> </ul>
2 3 4 5	Digitek, have you?  A. No, I've not been provided that. I've been provided evidence evidence that says that it's worth being investigated further. But I've not really been able to investigate it further.	2 3 4 5	<ul> <li>Q. And that's a statement of the FDA;</li> <li>right? Correct?</li> <li>A. Yes.</li> <li>Q. And it's a very important statement of the FDA, isn't it?</li> </ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Digitek, have you?  A. No, I've not been provided that. I've been provided evidence evidence that says that it's worth being investigated further. But I've not really been able to investigate it further.  Q. And you're a person who worked for and was trained by the FDA?  A. Yes.  Q. You had good training at the FDA?  A. I thought it was very, very good.  Q. Quality, competent people?  A. Yes.  Q. You have faith and confidence in the FDA?  A. Yes. I'm I'm I do understand all of the issues with other litigation. It's not my point to comment here.  This issue of how far I was to comment on this assessment has come up. I was told that leaving this comment in about the headquarters oversight was okay.  Q. Just follow me. Follow me here for a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And that's a statement of the FDA; right? Correct? A. Yes. Q. And it's a very important statement of the FDA, isn't it? A. Yes. Q. It speaks directly to the Digitek recall, doesn't it? A. Yes. Q. And it is a statement to the public about the Digitek recall; right? A. Yes. Q. The myth, as expressed by the FDA on Page 2, is that there are quality problems with generic drug manufacturing. They characterize that as a myth; right? A. Yes. Q. And they further say, as to the myth, A recent recall of generic Digoxin (called Digitek) shows that generic drugs put patients at risk. The FDA says that's a myth; correct? A. Yes. Q. And under Facts, the FDA says, In our best judgment, given the very small number of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Digitek, have you?  A. No, I've not been provided that. I've been provided evidence evidence that says that it's worth being investigated further. But I've not really been able to investigate it further.  Q. And you're a person who worked for and was trained by the FDA?  A. Yes.  Q. You had good training at the FDA?  A. I thought it was very, very good.  Q. Quality, competent people?  A. Yes.  Q. You have faith and confidence in the FDA?  A. Yes. I'm I'm I do understand all of the issues with other litigation. It's not my point to comment here.  This issue of how far I was to comment on this assessment has come up. I was told that leaving this comment in about the headquarters oversight was okay.  Q. Just follow me. Follow me here for a little bit.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. And that's a statement of the FDA; right? Correct? A. Yes. Q. And it's a very important statement of the FDA, isn't it? A. Yes. Q. It speaks directly to the Digitek recall, doesn't it? A. Yes. Q. And it is a statement to the public about the Digitek recall; right? A. Yes. Q. And it is a statement to the public about the Digitek recall; right? A. Yes. Q. The myth, as expressed by the FDA on Page 2, is that there are quality problems with generic drug manufacturing. They characterize that as a myth; right? A. Yes. Q. And they further say, as to the myth, A recent recall of generic Digoxin (called Digitek) shows that generic drugs put patients at risk. The FDA says that's a myth; correct? A. Yes. Q. And under Facts, the FDA says, In our

Videotaped

1 the lack of reported adverse events before the recall, harm to patients was very unlikely. 3 That's what the FDA says is a fact; 4 correct? 5 MR. THOMPSON: Object to the form. 6 THE WITNESS: That was my concern when I rated asking questions of is there any information that was never disclosed to you by plaintiffs' lawyers, were never revealed to you by plaintiffs' lawyers, were they? 4 A. No. And I will say — 5 Q. Were they? 5 A. Yes. 6 Q. And now you have seen the FDA's 1 statement as to this Digitek recall, haven't you? 15 A. Yes. 16 Q. And the FDA continues to stand by that 1 statement, don't they? 18 A. Yes. 19 Q. They haven't changed it since the recall, have they? 20 And so we come full circle; correct? 21 A. No, not — not on June 15th. 22 Q. And so we come full circle; correct? 23 A. Well, at this point, I have no inching else that would refute this statement, and detection. I can't tell you, and I have — I raised detection during the 204 to 2006. 5 If the FDA looked into that and there is nothing else that, then, you know, I can sit here with the evidence. 2 And if you say that the FDA has already done that, and said that, then, you know, I can sit here with the evidence. I will just be confirming 11 this. 2 Q. This is the FDA's bottom line statement; as to Digitek, isn't i? 4 A. Yes. 6 Py MR. KAPLAN: 7 D. Vou believe the FDA, don't you? 8 Q. Dottor, Jet me ask you to look at 25 Defendant's 38. 8 Page 267 1 Do you have that in front of you? 2 A. Yes. 9 Q. This is the FDA's bottom line statement; as to Digitek, isn't i? 4 MR. THOMPSON: Object to the form. 15 THE WITNESS: Yes. 16 BY MR. KAPLAN: 17 Q. You believe the FDA, don't you? 18 A. Yes. 19 Q. And this is the information — this is part of the information that was never disclosed to you by plaintiff's lawyers, were they? 2 A. And I did not sake it independently. 2 A. All did not offer what is the term and there is affected to me sentence in paragraph four of five bullet item of number three, bullet item number three. 2 Do you see that each time you'		7		Page 269
2 barm to patients was very unlikely.   3 That's what the FDA says is a fact;   4 correct?   5 MR. THOMPSON: Object to the form.   6 THE WITNESS: That was my concern when I ristarted asking questions of is there any information 8 that I can have that would tell me how — what is the percentage of any given batch affected, and what is the percentage of any given batch affected, and what is the chances that multiple pills ended up in one bottle?   2 BY MR. KAPLAN:   13 Q. And now you have seen the FDA's   14 statement as to this Digitek recall, haven't you?   15 A. Yes.   16 Q. And the FDA continues to stand by that statement, don't they?   18 A. Yes.   18 A. Yes.   18 Q. And so we come full circle; correct?   23 A. Well, at this point, I have no information on Digitek, per se, of any safety signal 25 detection. I can't tell you, and I have — I raised   24 G. Dottor, let me ask you to look at 25 Defendant's 38.   24 Q. Doctor, let me ask you to look at 25 Defendant's 38.   26 Q. Yes.   27 A. Near any the FDA's bottom line statement, I will never be able to refute it even if given the evidence.   3 A. Yes.   4 A. Yes.   5 A. Yes.		Page 266		Page 268
That's what the FDA says is a fact;  4 correct?  MR. THOMPSON: Object to the form.  6 THE WITNESS: That was my concern when I stated asking questions of is there any information in that I can have that would tell me how — what is the percentage of any given batch affected, and what is the percentage of any given batch affected, and what is the percentage of any given batch affected, and what is the percentage of any given batch affected, and what is the percentage of any given batch affected, and what is the percentage of any given batch affected, and what is the bottle?  12 BY MR. KAPLAN:  13 Q. And now you have seen the FDA's statement as to this Digitek recall, haven't you?  14 A. Yes.  15 Q. And the FDA continues to stand by that statement, don't they?  16 Q. And the FDA continues to stand by that statement, don't they?  17 A. No, not — not on June 15th.  18 A. Yes.  19 Q. They haven't changed it since the recall, have they?  20 R. Were they?  21 A. No, and I will say —  22 Q. And dow you have seen the FDA's statement in Exhibit 38, statements that I just read to you, are the truth.  23 A. Yes.  24 MR. THOMPSON: That you very much.  25 MR. THOMPSON: Well, I'm going to have some questions, or at least he did the other down asking questions, or at least he did the other down asking questions.  25 MR. THOMPSON: Well, I'm going to ask a few questions.  26 MR. THOMPSON: Well, I'm going to ask a few questions.  27 Page 267  1 this, and that's actually in my comments.  28 The issues with the pharmacovigilance system are broad. There was an absence of signal detection during the 2004 to 2006.  29 MR. THOMPSON:  20 Do you see that:  20 They haven't changed it since the seem of signal detection during the 2004 to 2006.  30 MR. THOMPSON:  40 Do you see that?  41 Do you have that in front of you?  42 A. Yes.  42 Do you see that?  43 A. Yes.  44 No. I did confirm when I took that and there is nothing the proper seem of signal detection during the 2004 to 2006.  44 Do you see that:  41 Do you see that cach time prounds t	1	<u>-</u>		
4 correct?  MR. THOMPSON: Object to the form. 6 MR. THE WITNESS: That was my concern when I started asking questions of is there any information that I can have that would tell me how — what is the percentage of any given batch affected, and what is the chances that multiple pills ended up in one bottle?  12 BY MR. KAPLAN: 13 Q. And now you have seen the FDA's statement as to this Digitek recall, haven't you? 15 A. Yes. 16 Q. And now you have seen the FDA's statement, don't they? 18 A. Yes. 19 Q. They haven't changed it since the recall, haven't changed it since the recall, have they? 21 A. No, not — not on June 15th. 22 Q. And so we come full circle; correct? 23 A. Well, at this point, I have no information on Digitek, per se, of any safety signal detection. I can't tell you, and I have — I raised  Page 267  1 this, and that's actually in my comments. 2 The issues with the pharmacovigilance system are broad. There was an absence of signal detection during the 2004 to 2006. 5 If the FDA looked into that and there is nothing else that would refute this statement, I will never be able to refute it even if given the evidence. 8 And if you say that the FDA has already of done that, and said that, then, you know, I can sit here with the evidence. I will just be confirming this. 10 Q. This is the FDA's bottom line statement as to Digitek, isn't i?  MR. THOMPSON: Object to the form. 15 THE WITNESS: Yes. 16 BY MR. KAPLAN: 17 Q. You believe the FDA, don't you? 18 A. Yes. 20 And this is the information — this is 20 part of the information that was never disclosed to you, are the truth? 21 A. Yes. 22 A. And I did not seek it independently. 23 A. Well, at this point, I have no information and there is nothing else that would refute this statement, I will never be able to refute it even if given the evidence.  8 And if you say that the FDA has already on the evidence. I will just be confirming this. 24 Q. This is the FDA's bottom line statement as to Digitek, isn't i?  25 Q. And this is the information — this is 20 part of	2	· · · · · · · · · · · · · · · · · · ·		
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THE WITNESS: That was my concern when I 7 started asking questions of is there any information 8 that I can have that would tell me how — what is the 9 percentage of any given batch affected, and what is 9 percentage of any given batch affected, and what is 10 the chances that multiple pills ended up in one 11 bottle?  12 BY MR. KAPLAN: 12 12 to you, are the truth?  13 Q. And now you have seen the FDA's 13 13 4 statement as to this Digitek recall, haven't you?  15 A. Yes. 15 MR. KAPLAN: 16 MR. KAPLAN: Thank you very much. MR. THOMPSON: The going to have some questions. I understand Mr. Moriarty objects to my asking questions, or at least he did the other day. MR. KAPLAN: Well, Mr. Moriarty isn't better. 19 here.  10 Q. And so we come full circle; correct? 21 A. No, not — not on June 15th. 22 Q. And so we come full circle; correct? 22 MR. Well, at this point, I have no 23 detection. I can't tell you, and I have — I raised 25 detection. Tean't tell you, and I have — I raised 25 detection. Tean't tell you, and I have — I raised 26 The inothing else that would refute this statement in Exhibit 38, statements that I just read to you, are the ruth? 26 MR. KAPLAN: Thank you very much. MR. THOMPSON: The going to have some questions. 1 was sing questions, or at least he did the other day. MR. KAPLAN: Well, Mr. Moriarty isn't here. 21 MR. KAPLAN: Well, Mr. Moriarty isn't here. 22 MR. KAPLAN: Well, Mr. Moriarty isn't here. 22 MR. THOMPSON: Well, I'm going to have some questions. 22 MR. THOMPSON: Well, I'm going to have some questions. 22 MR. THOMPSON: Well, I'm going to have some questions. 22 MR. KAPLAN: Thank you very much. MR. KAPLAN: Well, Mr. Moriarty isn't here. 21 MR. KAPLAN: Thank you very much. MR. KAPLAN: Thank you very much. MR. THOMPSON: Well, I'm going to have some questions, or at least he did the other day. MR. KAPLAN: Well, Mr. Moriarty isn't here. 22 MR. KAPLAN: Thank you very much. MR. KAPLAN: Thank you very	4			· · · · · · · · · · · · · · · · · · ·
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	22		ı	
	23		23	manufacturing current good manufacturing practice,
24 statement 24 parenthesis, CGMP regulations.	24	statement	ı	•
25 A. No. 25 Q. Now, read the entire bullet point number	25	A. No.	25	Q. Now, read the entire bullet point number

Videotaped

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1 four for me.

A. Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that all potentially infected lots have been recalled.

In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to the patients was very likely (sic).

Q. Now, do you believe that the FDA's judgment with regard to its determination of violation of good manufacturing practice would be as authoritative as that that you just answered Mr. Kaplan?

MR. DEAN: Objection to form, and also lack of expertise on inspection procedures, which she's already testified to.

MR. KAPLAN: I join that objection.

THE WITNESS: No. I had no way to come up with this conclusion that the FDA came up with because I had no information.

It was redacted out of the documents and I wasn't provided access to any information on analysis of the batches. I still think a lot was

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- about how to quantitate abnormal pills and lots, I can't tell you what procedure they should use.
- Q. Doctor, let me ask you a couple questions.

Do you know what period of Digitek drugs were recalled, for what time period?

A. It started June 6th, 2006, and I believe went for two years, up until the May -- or the April -- the date of the release of the recall. But I did look at that.

And I tried to sort it out because it had to do with -- it wasn't manufacture date, it was market release date.

Q. All right.

A. And I did take time to sort that out and then I was sort of out of scope.

Q. All right. Well, let me ask this: When this FDA facts and myths document was posted, was Digitek being made available to consumers in the United States?

A. When this was posted, I don't know what date it was posted. And I don't know whether Digitek was still in the market. I can't answer that. I was unable to find the date when he asked me for it.

Q. Well, if, assuming that the bullet point

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incinerated.

And there was no data mining of the database. We're assuming that when the FDA read this, that they were satisfied with the case reporting.

They did not go back and re-data mine that database.

6 BY MR. THOMPSON:

Q. Did you --

A. But I don't know. I have an absence of information.

And it's affecting -- it's clearly affecting my security at standing here and saying yes or no, because what I've been asked to render is very generalized, and I would prefer to have access to the remainder of that information.

Q. All right.

A. If, indeed, this is the bottom line, then I'm concerned that even if I asked for all the information, I won't come up with a different answer.

If this above there says, well, nobody ever looked at the lots before they ended up on the market and, therefore, this unlikely is based on, well, we never looked at the lots, that's what he's implying, that there is some uncertainty to that.

And now the question is, can I actually say -- because I'm not a GMP expert and I know nothing

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says lack of reported adverse events before the recall, can you date this as to when it was vis-a-vis the recall?

A. The recall package was dated April 25th, 2008. So it was up until that point. It was -- it was -- the press release was the 25th of April.

So you can say that up until public awareness of the recall on the 25th that there was no impact of the recall on the reporting rates.

So that the reporting rates up until the recall were not induced reporting rates. That as soon as that press release went out, the increase in reporting rates was significantly influenced by the knowledge of the recall.

And I cannot comment because I haven't looked at the cases. This is someone else.

Q. All right.

A. How many of those were potentially frivolous cases and how much were concerning -- how many cases do we have of documented supratherapeutic digitalis levels, how many cases took the tablet.

I do know that you can see digitalis toxicity at therapeutic doses. You don't have to be supratherapeutic to have the toxicity.

So it makes it very, very difficult to

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	Page 274		Page 276
1	sort out based on clinical symptoms whether you're	1	Q. You recall I think your testimony was
2	dealing with supratherapeutic digitalis.	2	you had not seen this before?
3	And I was very thankful that I did not	3	A. No.
4	have to render an expert opinion on that, that you	4	Q. Okay. Now, what's the date of the CGMP
5	probably took doctors who were experts in digitalis.	5	inspection?
6	Q. All right. That actually raises a	6	A. December 1st, 2004.
7	question.	7	Q. All right. Is there any date, is there
8	Is an adverse event report, is that	8	any operative date, that's been involved in any
9	voluntary or mandatory at the clinician's level?	9	question that you've been asked that includes
10	A. In the U.S., it's voluntary.	10	12/1/2004?
11	Q. If a practicing physician had a patient	1,1	A. No. However, the investigation report
12	who showed symptoms of Digoxin toxicity, would that,	12	for the double-thick Digitek tablet was July 2004.
13	as a common practice, generate an adverse event	13	Q. All right.
14	report?	14	A. I'm not sure what date. But it was five
15	MR. KAPLAN: Objection. Calls for	15	to six months before this repeat inspection.
16	hearsay.	16	Q. All right. And do you know the date of
17	THE WITNESS: Well, that's difficult to	17	production of this document to the plaintiffs in this
18	say.	18	case?
19	With a drug that's as old as Digoxin and	19	A. No. I do not know whether this was
20	as established, I can tell you right now that there	20	inadvertently omitted from my packet, whether it was
21	are hospital admissions for digitalis toxicity. That	21	in the millions of pages, some and not sent to me
22	when I was a resident I was not aware of MedWatches.	22	or whether it was sent to the plaintiffs late, and,
23	BY MR. THOMPSON:	23	therefore, we have evidence after I was submitted my
24	Q. All right.	24	dossiers
25	A. The issue when you're in a drug company	25	Q. All right.
	Page 275		Page 277
1	is that a post-marketing report in most companies	1	A that I should be allowed to consider
2	defaults to possible.	2	as later evidence.
3	By virtue of the fact that the person	3	Again, this is I keep saying my
4	had a clinical suspicion, when it's reported to the	4	naivete and maybe it's just my foolishness to say my
5	company, when you do that relatedness assessment	5	• • •
6	inside the company, many big pharma SOPs default to		naivete. But there may be issues with this. There
		6	naivete. But there may be issues with this. There may be late discovery that I would be permitted to
7		6 7	may be late discovery that I would be permitted to review without any embarrassment.
7 8	possible by virtue of the fact that the person who is	ŧ	may be late discovery that I would be permitted to
		7	may be late discovery that I would be permitted to review without any embarrassment.
8	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.	7 8	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull
8 9	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the	7 8 9	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.
8 9 10	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding	7 8 9 10	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.
8 9 10 11	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's	7 8 9 10 11	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.
8 9 10 11 12	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.	7 8 9 10 11	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get
8 9 10 11 12 13	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.  Q. All right. Let me ask you to look at	7 8 9 10 11 12	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.  MR. THOMPSON: Thank you.  THE WITNESS: I did ask
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8 9 10 11 12 13 14 15	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.  Q. All right. Let me ask you to look at Defendant's Number 20. I think it's on your it should be on your stack there.  No? It should be  MR. DEAN: This is a stack here, I was	7 8 9 10 11 12 13 14	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.  MR. THOMPSON: Thank you.  THE WITNESS: I did ask  BY MR. THOMPSON:  Q. The big appendix. The big appendix.
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8 9 10 11 12 13 14 15 16 17	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.  Q. All right. Let me ask you to look at Defendant's Number 20. I think it's on your it should be on your stack there.  No? It should be  MR. DEAN: This is a stack here, I was trying to get it organized. Let me find it for her.  Here you go.  BY MR. THOMPSON:	7 8 9 10 11 12 13 14 15 16 17 18 19 20	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.  MR. THOMPSON: Thank you.  THE WITNESS: I did ask  BY MR. THOMPSON:  Q. The big appendix. The big appendix.  A. Yes. I did ask if there was going to be more discovery, if discovery was complete, if all of these documents had been obtained, and if I could
8 9 10 11 12 13 14 15 16 17 18	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.  Q. All right. Let me ask you to look at Defendant's Number 20. I think it's on your it should be on your stack there.  No? It should be  MR. DEAN: This is a stack here, I was trying to get it organized. Let me find it for her.  Here you go.  BY MR. THOMPSON:  Q. All right. You were shown I'm going	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.  MR. THOMPSON: Thank you.  THE WITNESS: I did ask  BY MR. THOMPSON:  Q. The big appendix. The big appendix.  A. Yes. I did ask if there was going to be more discovery, if discovery was complete, if all of these documents had been obtained, and if I could request these missing documents in discovery, and they
8 9 10 11 12 13 14 15 16 17 18 19 20	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.  Q. All right. Let me ask you to look at Defendant's Number 20. I think it's on your it should be on your stack there.  No? It should be  MR. DEAN: This is a stack here, I was trying to get it organized. Let me find it for her.  Here you go.  BY MR. THOMPSON:  Q. All right. You were shown I'm going to hand you Defendant's 20. You were shown this	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.  MR. THOMPSON: Thank you.  THE WITNESS: I did ask  BY MR. THOMPSON:  Q. The big appendix. The big appendix.  A. Yes. I did ask if there was going to be more discovery, if discovery was complete, if all of these documents had been obtained, and if I could request these missing documents in discovery, and they said there may be that chance.
8 9 10 11 12 13 14 15 16 17 18 19 20 21	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.  Q. All right. Let me ask you to look at Defendant's Number 20. I think it's on your it should be on your stack there.  No? It should be  MR. DEAN: This is a stack here, I was trying to get it organized. Let me find it for her.  Here you go.  BY MR. THOMPSON:  Q. All right. You were shown I'm going to hand you Defendant's 20. You were shown this summary of findings of the CGMP inspection.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.  MR. THOMPSON: Thank you.  THE WITNESS: I did ask  BY MR. THOMPSON:  Q. The big appendix. The big appendix.  A. Yes. I did ask if there was going to be more discovery, if discovery was complete, if all of these documents had been obtained, and if I could request these missing documents in discovery, and they said there may be that chance.  Q. All right.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	possible by virtue of the fact that the person who is not subject to mandatory reporting reported the case.  So they default to submission to the FDA. There is some variability, but my understanding is the industry standard for post-marketing, when it's unsolicited, defaults to possible.  Q. All right. Let me ask you to look at Defendant's Number 20. I think it's on your it should be on your stack there.  No? It should be  MR. DEAN: This is a stack here, I was trying to get it organized. Let me find it for her.  Here you go.  BY MR. THOMPSON:  Q. All right. You were shown I'm going to hand you Defendant's 20. You were shown this	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	may be late discovery that I would be permitted to review without any embarrassment.  Q. All right. Now, let me ask you to pull out the big the attachment to your report.  MR. DEAN: Excuse me.  If we're done with that, let me get that one back in the stack of exhibits so it doesn't get misplaced.  MR. THOMPSON: Thank you.  THE WITNESS: I did ask  BY MR. THOMPSON:  Q. The big appendix. The big appendix.  A. Yes. I did ask if there was going to be more discovery, if discovery was complete, if all of these documents had been obtained, and if I could request these missing documents in discovery, and they said there may be that chance.

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Videotaped

witness, I was allowed to question this and ask for more information.  And that if I was provided it, that I could modify my report based on the submission of new	1 2	in content or in implementation to remediate the inspection findings of delinquent expedited reporting,
more information.  And that if I was provided it, that I	2	inspection findings of delinquent expedited reporting,
And that if I was provided it, that I		
	3	inadequate case follow-up, or the quality of reports.
could modify my report based on the submission of new -	4	Q. Okay. Now, if I hand you Defendant's
evidence to me.	5	Exhibit 87, which you saw for the first time today
That filing that report would not	6	during the and I'll just hand you my copy of it,
embarrass me, the Miller form, or Motley Rice, if	7	which you saw for the first time today, and you
another round of discovery would produce new evidence.	8	indicated that was one of the three documents that
Q. Okay. Let's go to Page 20 and 21 of	9	caused you to worry about your the quality of your
_		opinions.
	l	Do you see that?
· · · · · · · · · · · · · · · · · · ·	l	A. Yes.
	1	Q. And you agree that that's the letter
- ' "	l	that caused you to question that; is that right?
	l	A. Yes.
	l	Q. Okay. Read me the two sentences back to
		· · · · · · · · · · · · · · · · · · ·
	ı	back.
	1	Well, read me the entire second
· · ·	I	paragraph.  A. New Jersey District has reviewed your
-	i	A. New Jersey District has reviewed your response regarding the Adverse Drug Experience
	ı	reporting deficiencies. Your corrective actions and
	1	
	i	the revised procedures appear to be satisfactory.
~	I	We will, however, confirm the adequacy
A. August 15th, 2006 warning letter based	25	of your corrective actions and assess the overall ADE
Page 279		Page 281
on the company response dated February 28th, 2006.	1	reporting system during a future inspection.
So what happened with the 2006	2	Q. Okay. Now, what do you think the last
inspection is the company sent a response on February	3	sentence of that paragraph means?
28th to the 483, and then again on February 28th. And	4	A. They will confirm the implementation,
the FDA sent a revised warning letter and had	5	the adequacy of the implementation. At this point it
concerns.	6	appears they're okay with the content.
Q. All right.	7	They will confirm the adequacy of the
A. Yes.	8	implementation and they will expand the confirmation,
Q. Now, let's go to Page 21.	9	not just to the adequacy of the directed corrective
A. Okay.	10	actions to the observations in 2006
Q. And you have a comment on the following	11	Q. Okay.
-	12	A but they will expand this to include
A. All right.	13	the adequacy of the entire ADE system.
Q where you relate the and maybe I	14	Q. All right. Now
should just get you to read it. If we go down one,	15	A. This
two the sentence that begins In light of.	16	Q. Let me ask you a question.
Do you see that?	17	A. Okay.
A. Yes. Should I read the entire	18	<li>Q. I want to go back to your comment at</li>
	19	Page 21. Okay.
Q. Just read out loud the sentence that	20	Now, do you stand by your opinion that
begins with In light of.	21	was expressed on Page 21 that taking the findings of
A. In light of the FDA 483 inspection	22	the 2006 inspection and taking the findings of the
observations from May 20th, 2008, it is my opinion	23	2008 inspection that the compliance remediation was
based on reasonable degree of evidence that the	24	not adequate either in content or implementation to remediate the inspection findings?
-	that attachment.  A. Okay. Q. Now, there in the middle of the page of Page 20 there is a lengthy quotation.  A. Yes. Q. You see that? What is that quotation from?  A. It's from Reference 4 on Page 2. And Reference 4 is the August 15th warning letter based on the company response of February 28th. Q. And what day is that? MR. DEAN: What year? MR. THOMPSON: Yes. BY MR. THOMPSON: Q. What's the date? A. August 15th, 2006 warning letter based  Page 279  on the company response dated February 28th, 2006. So what happened with the 2006 inspection is the company sent a response on February 28th to the 483, and then again on February 28th. And the FDA sent a revised warning letter and had concerns. Q. All right. A. Yes. Q. Now, let's go to Page 21. A. Okay. Q. And you have a comment on the following page A. All right. Q where you relate the and maybe I should just get you to read it. If we go down one, two the sentence that begins In light of. Do you see that? A. Yes. Should I read the entire paragraph? Q. Just read out loud the sentence that begins with In light of.	that attachment.  A. Okay. Q. Now, there in the middle of the page of Page 20 there is a lengthy quotation. A. Yes. Q. You see that? What is that quotation from? A. It's from Reference 4 on Page 2. And Reference 4 is the August 15th warning letter based on the company response of February 28th. Q. And what day is that? Q. And what day is that? MR. DEAN: What year? MR. THOMPSON: Yes.  BY MR. THOMPSON: Q. What's the date? A. August 15th, 2006 warning letter based  Page 279  on the company response dated February 28th, 2006. So what happened with the 2006 inspection is the company sent a response on February 28th to the 483, and then again on February 28th. And the FDA sent a revised warning letter and had concerns. Q. All right. A. Yes. Q. Now, let's go to Page 21. A. Okay. Q. And you have a comment on the following page A. All right. Q where you relate the and maybe I should just get you to read it. If we go down one, two the sentence that begins In light of. Do you see that? A. Yes. Should I read the entire paragraph? Q. Just read out loud the sentence that begins with In light of.

	Page 282		Page 284
1	MR. DEAN: Objection.	1	entirety, provide evidence that the pharmacovigilance
2	MR. KAPLAN: I'm going to object and ask	2	system and the accompanying quality systems remain
3	for some clarification. I was told, I thought it was	3	inadequate to ensure compliance with regulatory
4	her sworn testimony, that Exhibit 261, that all of her	4	reporting or requirements of the compliance
5	opinions were contained in Section 3 entitled Analysis	5	remediation, either from the MHRA inspection of 2005
6	and Conclusions of Exhibit 261?	6	or the FDA inspections in the first quarter of 2006.
7	THE WITNESS: But I also stated that	7	I did not go into the specifics of the
8	this document was split in a very short time frame and	8	single-case reporting or the narrative quality. I
9	there was a chance that not all of them were	9	would have to go back and verify that.
10	completely transferred. I believe this is in 261.	10	But the when this really became a
11	MR. KAPLAN: Well, I'd like to have the	11	pressured situation to make a determination, I relied
12	reference to it because I'm trying to what I was	12	very, very heavily on this 2008 inspection to show
13	trying to do is figure out what are your opinions.	13	that there were persistent observations that were not
14	And I looked in the analysis section,	14	remediated.
15	and I'll just tell you that I looked for words such as	15	I couldn't say whether it was the
16	it is my opinion that or it is my opinion based on the	16	content of the plan because I wasn't provided that, or
17	evidence that.	17	the implementation. Because it could be a bad plan
18	And I counted, starting on Page 5, going	18	with good implementation or it could be a good plan
19	through Page 9, seven seven opinions that you	19	with bad implementation.
20	expressed in there. And so I did the best I could.	20	MR. KAPLAN: If there were remediation
21	Following that, I asked you the question	21	problems, do you think the FDA would have said in
22	are all your opinions contained in 261. Your answer	22	Exhibit 38 that there was a very it's very unlikely
23	was, yes, you relied upon that.	23	that anybody was harmed as the result of defective
24	So I just don't understand what it is	24	Digitek?
25	we're being asked to do here to try to suck out	25	MR. THOMPSON: Let me interrupt. It
	we to defing asked to do here to try to such out	<u> </u>	
		1	
	Page 283		Page 285
1	Page 283 opinions from another document that in your opinion	1	sounds as though we're going to go a little more than
1 2	-	1 2	
1	opinions from another document that in your opinion	ı	sounds as though we're going to go a little more than five minutes and he I think we're running out of tape.
2	opinions from another document that in your opinion MR. THOMPSON: This entire document was	2	sounds as though we're going to go a little more than five minutes and he I think we're running out of tape.  VIDEO OPERATOR: We have one left.
2 3	opinions from another document that in your opinion MR. THOMPSON: This entire document was produced timely. It's been in your possession. I'm	2	sounds as though we're going to go a little more than five minutes and he I think we're running out of tape.
2 3 4	opinions from another document that in your opinion MR. THOMPSON: This entire document was produced timely. It's been in your possession. I'm sure you've had people analyzing it. And the words have been in your possession for MR. KAPLAN: So you're telling me that	2 3 4	sounds as though we're going to go a little more than five minutes and he I think we're running out of tape.  VIDEO OPERATOR: We have one left.  MR. KAPLAN: Will you answer that question?
2 3 4 5	opinions from another document that in your opinion MR. THOMPSON: This entire document was produced timely. It's been in your possession. I'm sure you've had people analyzing it. And the words have been in your possession for MR. KAPLAN: So you're telling me that not all of her opinions are in Exhibit 261	2 3 4 5 6 7	sounds as though we're going to go a little more than five minutes and he I think we're running out of tape.  VIDEO OPERATOR: We have one left.  MR. KAPLAN: Will you answer that question?  MR. THOMPSON: Have I passed the chair
2 3 4 5 6	opinions from another document that in your opinion MR. THOMPSON: This entire document was produced timely. It's been in your possession. I'm sure you've had people analyzing it. And the words have been in your possession for MR. KAPLAN: So you're telling me that not all of her opinions are in Exhibit 261 THE WITNESS: I modified this.	2 3 4 5 6 7 8	sounds as though we're going to go a little more than five minutes and he I think we're running out of tape.  VIDEO OPERATOR: We have one left.  MR. KAPLAN: Will you answer that question?  MR. THOMPSON: Have I passed the chair to you?
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2 3 4 5 6 7 8	opinions from another document that in your opinion MR. THOMPSON: This entire document was produced timely. It's been in your possession. I'm sure you've had people analyzing it. And the words have been in your possession for MR. KAPLAN: So you're telling me that not all of her opinions are in Exhibit 261 THE WITNESS: I modified this. MR. KAPLAN: the June 15, 2010 document prepared by Dr. Karen A. Frank, entitled	2 3 4 5 6 7 8 9	sounds as though we're going to go a little more than five minutes and he I think we're running out of tape.  VIDEO OPERATOR: We have one left.  MR. KAPLAN: Will you answer that question?  MR. THOMPSON: Have I passed the chair to you?  No, wait. Go ahead. Go ahead. Go ahead.
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